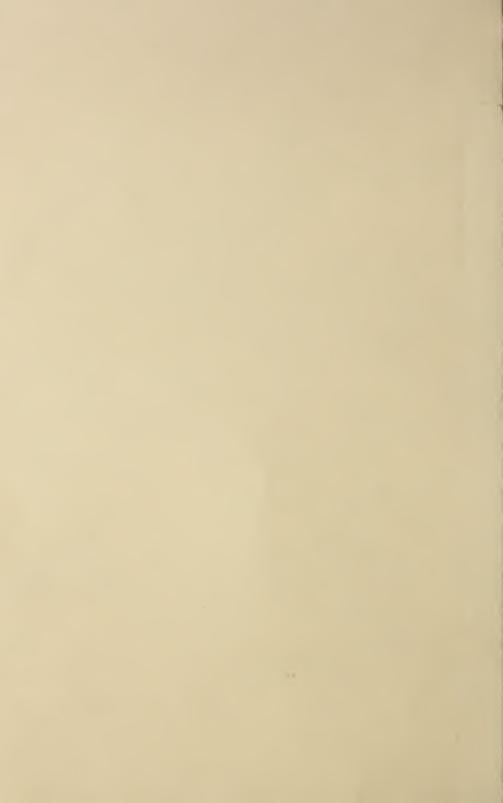
Historic, Archive Document

Do not assume content reflects current scientific knowledge, policies, or practices.



FEDERAL SECURITY AGENCY
FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 765 of the Food, Drug, and Cosmetic Act]

3201-3220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs.

WASHINGTON, D. C., January 2, 1951

CONTENTS *

Page			Page
Drugs actionable because of poten-	Drugs	and devices actionable be-	
tial danger when used accord-	ca	use of false and misleading	
ing to directions 188	cla	aims	196
Drugs actionable because of failure	Drug	gs for human use	196
to bear adequate directions or	Drug	gs for veterinary use	201
warning statements 190	Index_		203
Drugs and devices actionable be-			
cause of deviation from official			
or own standards 195			

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3202, 3204-3206; omission of, or unsatisfactory, ingredients statements, Nos. 3202, 3203, 3207, 3211, 3213, 3219; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3202-3207; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3202, 3204-3207; cosmetic, actionable under the drug provisions of the Act, No. 3215.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3201. Misbranding of procaine hydrochloride 2% and adulteration and misbranding of Salicyline No. 2 tablets. U. S. v. C. B. Kendall Co., Inc., Claude B. Kendall, and Ralph E. Monteith. Pleas of nolo contendere. Fines of \$1,800 against corporation, \$1,800 against defendant Monteith, and \$900 against defendant Kendall. (F. D. C. No. 28097. Sample Nos. 23084–K, 23086–K, 23441–K, 23774–K, 23776–K, 23778–K, 23973–K, 43464–K, 43465–K.)

Indictment Returned: On or about March 13, 1950, Southern District of Indiana, against C. B. Kendall Co., Inc., Indianapolis, Ind., Claude B. Kendall, president of the corporation, and Ralph E. Monteith, chief chemist for the corporation.

ALLEGED SHIPMENT: Between the approximate dates of February 23, 1948, and January 20, 1949, from the State of Indiana into the States of Louisiana, Texas, and Illinois.

Label, IN Part: "Procaine Hydrochloride 2% Kendall" and "Tablets Salicyline No. 2 * * * Kendall."

Nature of Charge: Procaine hydrochloride 2%. Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, "Average Dose: As required, inject subcutaneous or intradermal" and "Average Dose: As required, subcutaneous or intradermal," since such use of the article in such dosage and frequency may result in destruction of body tissue because of the actidity of the article.

Salicyline No. 2 tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain 5,000 units of vitamin D, whereas each tablet contained less than 5,000 units of vitamin D. Misbranding, Section 502 (a), the label statement "Each tablet contains: * * Vitamin D 5,000 units" was false and misleading.

DISPOSITION: On May 26, 1950, pleas of nolo contendere were entered on behalf of each of the defendants, and on July 14, 1950, after consideration of the written statements and oral comments of counsel, the court found the defendants guilty as charged and imposed the fines hereinbefore reported. In sentencing the defendants, the court made the following statement:

STECKLER, District Judge: "This case has certainly given the Court a great deal of concern, not by reason of the particular facts in this case, but in addition to that, this seems to be the home of some of the largest pharmaceutical manufacturers in the world. It is my understanding that this city is beginning to be known somewhat as a pharmaceutical city, along with Philadelphia and a few other large cities.

"I fully realize that the company, without penalty of the Court, will be seriously injured by reason of the civil actions which no doubt will be brought, claims that will be made. On the other hand, the Court can't lose sight of the fact that any company that is engaged in the drug business is under the strictest duty to maintain the integrity of that industry. The public has no way at all of protecting itself against the use of harmful drugs, if they are harmful, particularly when they are given under the prescription of the doctor, or injected by a doctor. Usually, I would say, the doctor in those circumstances would be innocent, too, if something was wrong with the drug.

"The penalty in a case like this, as far as punishing the corporation, would be, primarily, to serve as a reminder ever in the future to exercise the strictest policies in respect to the work of the personnel in reference to their particular duties, such as the measuring, the weighing, the checking and double checking. "I understand that the company has made extensive additions in the way of equipment since this alleged crime was committed. The Court is taking that

into consideration.

"I might also say that there are cases like this all over the United States that happen all the time with a drug company. I have had placed before me a number of judgments that have been rendered by other courts, not only by your counsel but by the counsel for the government. Fines are assessed from \$20 up to as high as a thousand dollars on a number of counts. Some of the

cases impose as high as \$15,000 penalty on these companies.

"As far as punishing the individuals, I think there is a growing trend on the part of the courts to begin to punish the individuals, those that actually have charge of the company, and the technicians in charge, by sentences. I think that is not the majority rule, however. Of course, most of the courts seem to take the other view and punish the defendants with monetary assessments against them. It has been very difficult for the Court to try to ascertain what would be a correct amount of penalty to impose in this case. The Court is taking into consideration the size of the company, the net income of the com-

pany, the fact that the company has made additions to its equipment.

"As I understand this case, it appears to me that it was somewhat of a case of negligence on the part of someone in the company in not checking the appa-

ratus that measured the amount of hydrochloric acid. . .

"The man that is president of the company must not only bear the penalties that go with operating the company, but he is also given the right to enjoy the benefits of being the head of the company. I think the one calls for the other. You have a right to enjoy the profits and the growth of the company as the president. Perhaps the owner of the company must also stand the penalties that come with it. It is hard to decide whether the president of the company, though he may not be actually involved in doing the thing, —making up the capsules, or measuring the chemicals and shipping them himself, — wrapping the packages, etc., — it is hard to decide whether or not he should be indicted.

"I am inclined to think that the intent of the law is to keep the same company from doing the same thing over, more so than to deter others from doing it, because in a scientific industry like this, they are constantly making new developments, and I think the reason that the penalty is imposed is to make that particular company ever mindful of the fact that they must check and double check. I understand that some of the daug firms make three different types of checks whenever they have a complaint, and that prior to this offense, this company did not do that, did not make the different types of analyses, and that now, however, you are making the various types of analyses.

"All those things indicate progress as far as the drug industry is concerned, the pharmaceutical profession. I know some of the largest in the country have had penalties against them. I have gone back and looked in the record. I have found practically all of them have had penalties assessed at one time

or another."

"Mr. Cox. But not the President. I haven't seen any where the President has."

"The Court. There have been a number where the officials have .

"Even in the food industry I found a case where the Roma Macaroni Company had ten thousand dollars assessed against the President, a similar fine assessed against one of the other officials, or against the corporation. One of the technicians was released.

"I realize that under the law, intent is not an element in this case. That may be unfortunate from the standpoint of the defendant, but from the standpoint of the public it is a safeguard, and the mere fact that the drug reaches the status of being in interstate commerce, then and there you are guilty of having committed a pure food and drug law violation if the transaction comes within the scope of the act.

"Well, this is a case involving ten counts against each of these defendants, and if one were to sit down and figure up the maximum that could be imposed, the Court could virtually put the company out of business, but the Court,

under the circumstances, has no such intention.

"It is a matter in which the Court feels, however, that the company should pay a penalty sufficient that the public will fully realize they are being

protected by the courts. It is a case, by the same token, where the company will have a reminder in the future to guard against the occurrence of the

same thing.

"I don't believe that these men are criminals. They don't look like it; they don't appear to be criminals; I don't think there is anything criminal about them. It is a matter where they are engaged in a business that has a lot of hazards and we are all free to choose the type of business we would like to go into.

"So, it is the judgment of the Court, based upon the findings of the Sourt in this case, there having been a plea of nolo contendere made in the case, that the defendant, the C. B. Kendall Company, Inc., is guilty as charged in the indictment, and that the defendant corporation be fined in the sum of \$100 on the first eight counts of the indictment, and that the defendant corporation

be fined in the sum of \$500 each on each of the last two indictments.

"I might explain that under the law the penalty could be twice the sum provided in the Act. The Act provides \$1,000. I am merely explaining that to show you that as far as the Court is concerned, you are not being given the absolute maximum penalty. I am making no apologies. It is a matter that the Court feels they should pay this additional penalty as a corporation.

"It is the judgment of the Court, based upon the plea of Defendant Ralph E. Monteith, his plea being that of nolo contendere, and the finding of the Court in this case, that the defendant Ralph Monteith is guilty as charged in the indictment and that he be sentenced to pay a fine in the amount of \$100 on each of the first eight counts and that he be sentenced to pay a fine of \$500

on each of the last two counts, Counts 9 and 10.

"It is the judgment of the Court, based upon the plea of the Defendant Claude B. Kendall, and based upon the findings of the Court that the Defendant Claude B. Kendall is guilty as charged in the indictment, that he be sentenced to pay a fine of \$50 on each of the first eight counts, and that he be sentenced to pay a fine of \$250 on each of the last two counts.

"Do you understand the fines?"
"The DEFENDANTS. Yes, sir."

"The COURT. That is almost a \$5,000 fine. I feel it is reasonable. I don't think it is too low; I don't think it is too high for a company of this size. I do believe this company will gain by this experience in the future."

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3202. Alleged misbranding of Benadryl capsules, Benzedrine Sulfate tablets, Dexedrine Sulfate tablets, and phenobarbital tablets. U. S. v. Earl S. Fitzgerald (Fitzgerald Drug Store). Plea of nolo contendere. Case dismissed by court. (F. D. C. No. 26731. Sample Nos. 46195-K, 46196-K, 46229-K, 46230-K, 46438-K, 46439-K.)

Information Filed: September 23, 1949, Eastern District of Arkansas, against Earl S. Fitzgerald, trading as the Fitzgerald Drug Store, Corning, Ark.

INTERSTATE SHIPMENT: Between the approximate dates of May 10 and November 9, 1948, from St. Louis, Mo., and Cairo, Ill., into the State of Arkansas.

ALLEGED VIOLATION: On or about January 21 and 22 and February 1, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Alleged misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions for use. "As Directed" on the labeling of the *Benadryl capsules*, "One 9 A. M. and 3 P. M."

on the labeling of the *Benzedrine Sulfate tablets*, and "One Tablet night and morning" on the labeling of one sale of the *Dexedrine Sulfate tablets*, were not adequate directions for use, and since the labeling of the other sale of *Dexedrine Sulfate tablets* and *phenobarbital tablets* bore no directions for use.

Further misbranding, Section 502 (e) (1), the labeling of the repackaged Benadryl capsules, Benzedrine Sulfate tablets, one sale of Dexedrine Sulfate tablets, and one sale of phenobarbital tablets, failed to bear the common or usual names of the drugs.

Further misbranding, Section 502 (d), the *phenobarbital tablets* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative has been, by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Disposition: November 28, 1949. A plea of nolo contendere was entered by the defendant. The defendant's attorney informed the court that he had advised the defendant that such sales were not in violation of the law, and that the defendant had acted on the advice of counsel in making the sales. Thereupon, the court ordered the information dismissed.

- 3203. Misbranding of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets.

 U. S. v. John H. Hugg. Plea of nolo contendere. Fine of \$100, plus costs.

 (F. D. C. No. 29423. Sample Nos. 61424-K, 61756-K.)
- Information Filed: June 28, 1950, Western District of Kentucky, against John H. Hugg, a partner and pharmacist in the partnership of Hugg, The Druggist, at Paducah, Ky.
- INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of Kentucky, of quantities of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about September 28 and 29, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused portions to be repacked and sold without a prescripton, which acts resulted in the drugs being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), both repackaged drugs failed to bear labels containing a statement of the quantity of the contents;

 Section 502 (e) (1), the repackaged Benzedrine Sulfate tablets bore no label containing the common or usual name of the drug; and, Section 502 (f) (1), both repackaged drugs failed to bear labeling containing adequate directions for use in that the labeling of the repackaged Dexedrine Sulfate tablets bore no directions for use, and the directions "Take as directed by physician," borne on the labeling of the repackaged Benzedrine tablets, were not adequate directions for use.
- Disposition: July 14, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100, plus costs.
- 3204. Misbranding of Dexedrine Sulfate tablets, Nembutal Sodium capsules, and thyroid tablets. U. S. v. Louis R. Hugg (Hugg's Drugs). Plea of nolo contendere. Fine of \$200, plus costs. (F. D. C. No. 29425. Sample Nos. 61648–K, 61660–K, 61681–K, 61682–K.)
- Information Filed: June 13, 1950, Western District of Kentucky, against Louis R. Hugg, trading as Hugg's Drugs, Paducah, Ky.

INTERSTATE SHIPMENT: From the States of Pennsylvania, Missouri, and Indiana, of quantities of *Dexedrine Sulfate tablets*, *Nembutal Sodium capsules*, and *thyroid tablets*.

ALLEGED VIOLATION: On September 14 and 29, 1949, the defendant sold without a prescription, in the original bottles in which the articles had been shipped in interstate commerce, and while they were held for sale by the defendant after such shipment, one bottle containing 24 Dexedrine Sulfate tablets and one bottle containing 50 thyroid tablets. The tablets contained in the original bottles had been exempt from the requirement of Section 502 (f) (1), prior to the date of such sales, since their labels bore the prescription legend required by the regulation. This exemption expired when the defendant sold the tablets without physician's prescription, and resulted in the misbranding of the tablets in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

On September 17 and 29, 1949, while the Nembutal Sodium capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged and sold without a prescription, which acts of the defendant resulted in the product being misbranded as follows: Sections 502 (b) (1) and (2), the repackaged capsules failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents. Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been designated as habit forming; and when repackaged the drug bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of a portion of the capsules bore no directions for use, and the directions "One at bedtime" borne on the labeling of another portion of the capsules were not adequate directions for use.

Disposition: July 20, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$200, plus costs.

3205. Misbranding of Nembutal Sodium capsules, phenobarbital tablets, and thyroid tablets. U. S. v. Mary S. Northrup (Northrup Drug Store). Plea of nolo contendere. Fine, \$125. (F. D. C. No. 28113. Sample Nos. 45597-K, 46061-K, 46068-K, 60795-K, 60797-K.)

Information Filed: February 17, 1950, Western District of Missouri, against Mary S. Northrup, trading as the Northrup Drug Store, Rich Hill, Mo.

INTERSTATE SHIPMENT: From North Chicago, Ill., Detroit, Mich., and Indianapolis, Ind., into the State of Missouri, prior to May 11, 16, and 24, 1949.

ALLEGED VIOLATION: On or about May 11, 16, and 24, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendant caused quantities of the articles to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged articles being misbranded.

Nature of Charge: Misbranding, Section 502 (b) (1), the repackaged articles bore no label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), they bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged Nembutal Sodium capsules and phenobarbital tablets were drugs for use by man and contained

chemical derivatives of barbituric acid, which derivatives have been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules and tablets failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged Nembutal Sodium capsules and thyroid tablets failed to bear labeling containing adequate directions for use.

- DISPOSITION: March 3, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$125.
- 3206. Misbranding of Seconal Sodium capsules. U. S. v. John Byron Miller (J. B. Miller, pharmacist). Plea of guilty. Fine of \$225, plus costs. (F. D. C. No. 28130. Sample Nos. 43664–K, 43665–K, 51668–K.)
- Information Filed: May 18, 1950, Eastern District of Kentucky, against John Byron Miller, trading as J. B. Miller, pharmacist, Williamstown, Ky.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of Kentucky, of quantities of Seconal Sodium capsules.
- ALLEGED VIOLATION: On or about June 14, 17, and 20, 1949, while the Seconal Sodium capsules were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the capsules to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged capsules being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and when repackaged, the drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

- DISPOSITION: September 25, 1950. A plea of guilty having been entered, the court imposed a fine of \$225, plus costs.
- 3207 Misbranding of sulfathiazole tablets. U. S. v. Herman V. Baker (Baker's Cut Rate Drugs). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 29119. Sample Nos. 48642-K, 48657-K, 48658-K.)
- Information Filed: June 8, 1950, Eastern District of Pennsylvania, against Herman V. Baker, trading as Baker's Cut Rate Drugs, Philadelphia, Pa.
- INTERSTATE SHIPMENT: From the State of New York into the State of Pennsylvania, of quantities of *sulfathiazole tablets*.
- Alleged Violation: On or about October 24 and 28 and November 3, 1949, while the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), they bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: August 17, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$300.

3208. Misbranding of methyl testosterone tablets and alpha estradiol tablets. U. S. v. Norman N. Beil (Research Products). Plea of guilty. Fine of \$800, plus costs. (F. D. C. No. 28120. Sample Nos. 2780-K, 3779-K, 12349-K, 24998-K.)

Information Filed: January 25, 1950, Northern District of Ohio, against Norman N. Beil, trading as Research Products, Cleveland, Ohio.

ALLEGED SHIPMENT: On or about January 27, 28, and 31, and February 10, 1949, from the State of Ohio into the States of Maryland, Virginia, Delaware, and South Dakota.

LABEL, IN PART: (Methyl testosterone tablets). "Male Hormone Tablets Each Tablet Contains 10 mg. [or "5 mg."] Methyl Testosterone For use when Methyl Testosterone is indicated for symptoms of Male Hormone Deficiency. Suggested Average Dose: One (1) tablet daily when the use of male hormones is directed by your physician. Warning: The male sex hormone should not be used if there is any indication of cancer of the prostate."

Accompanying 2 of the 3 shipments of methyl testosterone tablets were circulars entitled "The Male Hormone," and one of these shipments also was accompanied by an instruction sheet entitled "Important Instructions." The label of the alpha estradiol tablets (female hormones) had been destroyed by the consignee, but the consignment was accompanied by a copy of the circular entitled "The Male Hormone," which contained certain representations regarding the female hormone.

NATURE OF CHARGE: Methyl testosterone tablets. Misbranding, Section 502 (a), (2 shipments) certain statements in the labeling were false and misleading. The labeling represented and suggested that the article would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development, and depth of voice; that it would correct lack of sexual power and impotence; that it would relieve and postpone the many conditions associated with middle age, and would improve the sense of well-being; that it constituted for the average man in his late forties an adequate treatment for flushes, sweats, chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression and general weakness, and poor physical strength; that the use of the article would result in improved physical and mental work, and would exert a tonic action resulting in renewed vigor; and that the article would impart a better attitude toward social life, and would cause nervousness, exhaustion, and melancholy to disappear. The article would not be effective for such purposes. Further misbranding, Section 502 (f) (1), (all shipments) the labeling failed to bear adequate directions for use in that the directions for use appearing in the labeling were inadequate.

Further misbranding, Section 502(f)(2), (2 shipments) the labeling failed to bear adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since each tablet contained 10 milligrams of methyl testosterone; and the labeling of the article failed to bear adequate warnings against use by individuals who may have cancer of the prostate since the ordinary lay user is not familiar with the indications of cancer of the prostate.

Alpha estradiol tablets. Misbranding, Section 502(a), certain statements in the labeling, i. e., in the accompanying circular entitled "The Male Hormone," were false and misleading. The labeling represented and suggested that the article would relieve and postpone the many conditions associated with middle age, and that the article constituted an adequate treatment for hot flashes, emotional disturbances and other manifestations associated with the menopause. The article would not be effective for such purposes.

DISPOSITION: March 24, 1950. A plea of guilty having been entered, the court fined the defendant \$800, plus costs.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3209. Adulteration and misbranding of adhesive bandages. U. S. v. 180 Cartons, etc. (and 2 other seizure actions). (F. D. C. Nos. 28995, 29235, 29272. Sample Nos. 46598–K, 46599–K, 47244–K, 47245–K, 47547–K.)

LIBELS FILED: April 25, May 19, and June 14, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 2, April 17, and May 1, 1950, by the Seamless Rubber Co., from New Haven, Conn.

PRODUCT: Adhesive bandages. 540 cartons, each containing 12 tins, 23 boxes, each containing 720 tins, and 780 cartons, each containing 12 tins, at Pittsburgh, Pa.

Label in Part: "Quik-Bands Assorted Sterilized Plain [or "Quik-Bands Assorted with Mercurochrome * * * Sterilized"] * * * Adhesive Bandages" and "Rexall First Aid Quik-Bands Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statements "Sterile," "First Aid," and "Sterilized" were false and misleading as applied to an article that was not sterile.

Disposition: July 21 and August 4, 1950. The Seamless Rubber Co. having appeared as claimant for the lot of 540 cartons and the lot of 23 boxes and consented to the entry of decrees, judgments of condemnation were entered and the court ordered that such lots be released under bond to be brought into compliance with the law by resterilization. In the matter of the lot of 780 cartons, only 60 cartons were on hand at the time of seizure. No claimant

^{*}See also No. 3201.

⁹¹⁷⁹⁵⁹⁻⁵¹⁻²

having appeared for the 60 cartons, the court entered a default decree of condemnation and destruction.

3210. Adulteration and misbranding of prophylactics. U. S. v. 63 Cartons * * * (F. D. C. No. 28994. Sample No. 50851-K.)

LIBEL FILED: April 28, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about March 23, 1950, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

PRODUCT: 63 cartons, each containing 12 packages, of prophylactics at Seattle, Wash. Examination of samples showed that 5.3 percent were defective in that they contained holes.

LABEL, IN PART: (Package) "12 Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "For Your Protection * * * An Aid In Preventing Venereal Disease" were false and misleading as applied to an article containing holes.

Disposition: September 29, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3211. Misbranding of Imdrin. U. S. v. 2,100 Bottles * * *. (F. D. C. No. 26977. Sample No. 20470-K.)

LIBEL FILED: On or about April 14, 1949, Western District of Missouri; amended libel filed on February 2, 1950, Southern District of Ohio.

ALLEGED SHIPMENT: On or about December 21, 1948, and January 5, 7, and 14, 1949, by the Rhodes Pharmacal Co., Inc., from Cleveland, Ohio.

PRODUCT: 2,100 72-tablet bottles of Imdrin at Kansas City, Mo. Examination disclosed that each tablet of a portion of the product contained 2 grains of aspirin, 1.4 grains of manganese salicylate, 2.3 grains of calcium succinate, 0.19 grain of caffeine, and some thiamine, and that each tablet of the other portion of the product contained 2 grains of aspirin, 1.6 grains of sodium salicylate, 1.56 grains of calcium succinate, 0.16 grain of caffeine, and 1 mg. of thiamine.

LABEL, IN PART: "Imdrin * * * Each tablet contains: Manganese Salicylate, Calcium Succinate, Acetylsalicylic Acid, Thiamine Chloride (1 mg.) and Caffeine" or "Imdrin * * * Each tablet contains: Sodium Salicylate, Calcium Succinate, Acetylsalicylic Acid, Thiamine Chloride (1 mg.) and Caffeine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs appearing in the labeling of the article, namely, on a placard entitled "Rheumatic-Arthritic Sufferers," in a leaflet entitled "Amazing New Imdrin," and on a sheet entitled "Imdrin Fastest Selling Most Heavily Advertised Rheumatic-Arthritic Item," were false and misleading. The statements and designs represented and suggested that the article was adequate and effective for the treatment and cure of all types of arthritis and rheumatism; that the article contained no drugs; that it would give the fastest pain relief in

^{*}See also Nos. 3201, 3208-3210.

rheumatic and arthritic cases; that it would enable one to resume comfortable, normal living; that it would enable sufferers to gain relief, even after 20 years of pain and torture; that it would enable one to move about without pain and enjoy life again; that it would aid in the relief of nagging aches, pains, swelling, and stiffness accompanying arthritis and related illness, such as certain types of rheumatism, sciatica, bursitis, and neuritis; that it was one of the fastest and safest remedies known for alleviating the miseries of the rheumatoid state and arthritis, and was an efficient medicament for the relief of the symptoms of such infirmities; that users of the article would have no more "Blue Days," and would resume a cheerful outlook on life; that the article would aid sufferers from gout to regain a comfortable living status; that it would assist in the relief from the discomfort of neuritis, aid in maintaining the feeling of well-being, and aid in insuring adequate functioning of the vital enzyme systems of the blood and bones; and that it would bring symptomatic relief to sufferers from arthritis, fibrositis, and certain forms of rheumatism, sciatica, and neuritis. The article was not adequate and effective for the treatment and cure of all types of arthritis and rheumatism; it contained drugs; and it was not capable of fulfilling the promises of benefit stated and implied.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of aspirin, an active ingredient.

The article was misbranded in the above respects when introduced into, while in, and while held_for sale after shipment in, interstate commerce.

DISPOSITION: April 26, 1950. The libel proceedings having been transferred to the Southern District of Ohio, and the Rhodes Pharmacal Co., Inc., claimant, having filed an answer denying that the article was misbranded, but subsequently without admitting the misbranding, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the labeling of the product be destroyed and that the bottles of the product be delivered to a charitable hospital or institution for use under the supervision of physicians, as a simple analgesic. On June 14, 1950, the decree was amended to allow destruction of the product.

3212. Misbranding of thyroid tablets. U. S. v. 136 Dozen Bottles, etc. (F. D. C. No. 28702. Sample No. 54179–K.)

LIBEL FILED: On or about February 8, 1950, Northern District of Texas.

ALLEGED SHIPMENT: On or about August 9 and September 28, 1949, by the Kalamazoo Pharmacal Co., Kalamazoo, Mich.

PRODUCT: Thyroid tablets. 136 dozen 50-tablet bottles and 8 dozen 100-tablet bottles at Dallas, Tex., in possession of the Sims Pharmacal Co.

RESULTS OF INVESTIGATION: This product was shipped, labeled as described below. A number of circulars which had been printed locally and which were entitled "There Is Relief For High And Low Blood Pressure," were in possession of the consignee. These circulars were given to prospective customers and were being mailed to persons inquiring about the product. The consignee had on display in the office a cardboard display stand holding six bottles of the product, four copies of the above-named circular, and a poster entitled "Drug is Discovered."

LABEL, IN PART: "Boaz's Tablets * * * Each tablet contains: Ext. Thyroid 1/500 gr. and Ext. Parathyroid, Ext. Pituitary, Calcium Lactate, and Sodium Bicarbonate,"

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements which appeared on the bottle label "in the treatment of abnormal Blood Pressure and following Symptoms: Headaches, dizziness, pains in back of head and neck, and cramping in the legs" were false and misleading since the product would not be effective in the treatment of abnormal blood pressure or of the symptoms stated. The product was misbranded in the above respect when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (a), the statements in the circulars entitled "There Is Relief For High And Low Blood Pressure," on the cardboard display stand, and on the display poster entitled "Drug is Discovered," which accompanied the article and which represented and suggested that the article was effective in the treatment of high and low blood pressure, were false and misleading since the article would not be effective in the treatment of such conditions. The product was misbranded in the latter respect while held for sale after shipment in interstate commerce.

DISPOSITION: March 7, 1950. Default decree of condemnation and destruction.

3213. Misbranding of Pep tonic, Taj Quality tetter salve, Taj Superior balm, and Hindu Magic liniment. U. S. v. 17 Bottles, etc. (F. D. C. No. 29050. Sample Nos. 56869-K to 56872-K, incl.)

LIBEL FILED: April 11, 1950, District of New Jersey.

ALLEGED SHIPMENT: On or about October 4, November 28, and December 12, 1949, and February 10 and 16, 1950, by the Taj Perfume Co., from Detroit, Mich.

PRODUCT: 17 8-fluid-ounce bottles of Pep tonic, 2 2-ounce jars of Taj Quality tetter salve, 33 2-ounce jars of Taj Superior balm, and 78 2-ounce bottles of Hindu Magic liniment, at Newark, N. J.

Analysis disclosed that the *Pep tonic* consisted essentially of hypophosphites of calcium, sodium, and potassium, and alcohol, sugar, flavor, coloring, and water; that the Taj Quality tetter salve consisted essentially of sulfur, resorcinol, and menthol salicylate in a petrolatum base; that the Taj Superior balm consisted essentially of essential oils such as eucalyptol, methyl salicylate, menthol, and thymol in a petroatum base; and that the Hindu Magic liniment consisted essentially of essential oils, chloroform, isopropyl alcohol, water, and a red coloring matter.

Label, in Part: "Pep Tonic * * * East & West Herbs Laboratory," "Taj Quality Tetter Salve," "Taj Superior Balm," and "Hindu Magic Liniment."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading since they represented and suggested that the articles would be effective for the treatment of the conditions stated and implied, whereas they would not be effective for such purposes: (Pep tonic) "Pep Tonic * * * to enrich blood cells, strengthen the nerves, and impart vitality into the entire system * * * for anemic, weak, low, vitality, rundown and nervous condition," (Taj Quality tetter (Taj Superior balm) "For Colds and Sorethroat," and (Hindu Magic liniment) "Marvelous in Stopping Pains Instantly. Unequaled for Rheumatism, Sore stiff joints * * * Toothache * * * Head or Chest-Colds, Pneumonia * * * Corns and Bunions."

Further misbranding, Section 502 (e) (2), the label of the Pep tonic failed to bear the quantity, kind, and proportion of alcohol contained therein; and the labels of the remaining products failed to bear the common or usual name of each active ingredient, including, in the case of the *Hindu Magic liniment*, the quantity, kind, and proportion of alcohol and the quantity of chloroform contained therein.

DISPOSITION: May 29, 1950. A default decree of condemnation was entered, and the court ordered that a number of bottles and jars of each product be delivered to the Food and Drug Administration, and that the balance be destroyed.

3214. Misbranding of Raysol. U. S. v. 1,339 Bottles, etc. (F. D. C. No. 28745. Sample No. 73192–K.)

LIBEL FILED: March 13, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about June 15 and September 16, 1949, from Washington, D. C.

PRODUCT: 1,339 6-ounce bottles of Raysol at New York, N. Y., in possession of the Raysol Distributing Corp., together with a number of circulars entitled "Here Is Nature's Own Way To Good Health," which were printed locally. Examination of the article indicated that it was mineral water containing various minerals and an inconsequential amount of radium.

Nature of Charge: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading. These statements represented and suggested that the article was effective in the treatment of rheumatism, arthritis, neuritis, sciatica, lumbago, joint and muscular pains and aches, ulcers, indigestion, gastritis, constipation, psoriasis, kidney and bladder troubles, stomach troubles, high blood pressure, circulatory disorders, diabetes, anemia, angina pectoris, loss of appetite, skin blemishes, general debility, skin eruptions, leg pains, loose teeth, and sore gums; that the article contained a consequential amount of radium; and that the article was comparable in mineral constituents to the human blood. The article was not effective in the treatment of the symptoms, diseases, and conditions stated and implied; it did not contain a consequential amount of radium; and it was not comparable in mineral constituents to human blood.

The article was misbranded while held for sale after shipment in interstate commerce.

Disposition: May 5, 1950. The Raysol Distributing Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond, providing that the labels on the 6-ounce-size bottles and the accompanying circulars be destroyed; that the product be rebottled into 16-ounce-size bottles; and that the larger bottles be labeled in compliance with the law.

3215. Misbranding of Glorion. U. S. v. 114½ Dozen Bottles * * *. (F. D. C. No. 28753. Sample No. 21578-K.)

LIBEL FILED: On or about March 20, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about January 10, 1950, by the Glorion Corp. of America, from Beverly Hills, Calif.

PRODUCT: 114½ dozen bottles of *Glorion* at Kansas City, Mo. Examination disclosed that the product consisted essentially of a fatty oil, with small proportions of cholesterol and perfume.

LABEL, IN PART: "Glorion The One Drop Beauty Treatment."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular in the package containing the article were false and misleading since the article was not effective in accomplishing the purposes and results stated and implied: "* * * In some people the processes of cell and gland activity go on normally in spite of clogged pores, sunburn and the like. In others these processes need a little help, a little stimulation. Because of improper nourishment, skin may become puffy, wrinkled; because of inactivity, pores clog and cause blackheads, dryness or oiliness. * * * Glorion was formulated to go deep down, work within the skin, revitalizing cells and glands. It contains millions of electro-chemically activated molecules of vital skin cell substances. It helps cells and glands to resume their normal functions so that they may resist the elements, absorb proper nourishment, and help regain firm facial tone, colorful radiance and a smoother texture of the skin. Activated hormonic substances, dihydrocholesterols, isomers, and related sterols of natural origin. * * * Glorion was formulated so that the skin could feed hungrily on its revitalizing substances. * * * it stimulates * * * pores * * * It contains substances * * * considered vital to skin health. * * * No More Large Pores * * * Blemishes Vanished Blackheads Disappeared Wrinkles Gone * * * Corrected My Abnormally Oily Skin * * *."

DISPOSITION: April 10, 1950. The Glorion Corp. of America, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. The product subsequently was relabeled.

3216. Misbranding of witch hazel. U. S. v. Approved Products, Inc. (Windsor Chemical Laboratories). Plea of nolo contendere. Fine, \$100. (F. D. C. No. 29125. Sample Nos. 13400-K, 13421-K.)

Information Filed: May 8, 1950, Eastern District of Pennsylvania, against Approved Products, Inc., trading as the Windsor Chemical Laboratories, Philadelphia, Pa.

Interstate Shipment: On or about July 25, 1949, from the State of Connecticut into the State of Pennsylvania, of a quantity of witch hazel.

ALLEGED VIOLATION: Between the approximate dates of July 29 and August 11, 1949, while the witch hazel was being held for sale after shipment in interstate commerce, the defendant caused a quantity of the drug to be repacked into bottles bearing a mineral oil label and caused such bottles to be sold, which acts resulted in the drug being misbranded.

LABEL, IN PART: "Lane Extra Heavy Mineral Oil."

Nature of Charge: Misbranding, Section 502 (a), the label statement "Mineral Oil" was false and misleading since the article in the bottles did not consist of mineral oil but consisted of witch hazel.

DISPOSITION: September 26, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100.

3217. Misbranding of Hollywood Vita-Rol device. U. S. v. 60 Cartons, etc. (F. D. C. No. 28993. Sample No. 71666-K.)

LIBEL FILED: May 3, 1950, Northern District of Texas.

Alleged Shipment: On or about April 11, 1950, by the S & D Engineering Co., from Glendale, Calif.

PRODUCT: 60 cartons each containing 1 Hollywood Vita-Rol device and a circular entitled "Reduce Relax Rejuvinate" at Dallas, Tex. Examination showed that the device consisted of an electrically heated roller covered with corrugated rubber.

LABEL, IN PART: "Hollywood Vita-Rol Model A 125 Volts 76 Watts."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular accompanying the device were false and misleading since the device was not effective for the purposes represented, and was not an effective treatment for the conditions represented. The statements represented and suggested that the device was effective for spot reducing, rejuvenating, poor circulation, constipation, and insomnia, and that it was effective as a body conditioner and as a treatment for muscular soreness.

DISPOSITION: August 8, 1950. The libel proceedings having been removed to the Southern District of California, and the S & D Engineering Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3218. Misbranding of Denhalant, Arsiden, Dencolten, and Rex wheat germ oil. U. S. v. 60 Bottles, etc. (F. D. C. No. 25355. Sample Nos. 25505-K to 25508-K, incl., 25510-K, 25511-K.)

LIBEL FILED: August 25, 1948, District of South Dakota.

ALLEGED SHIPMENT: Between the approximate dates of June 21, 1947, and March 26, 1948, Vet Products, Inc., shipped a number of bottles of Denhalant, Arsiden, and Dencolten from Kansas City, Mo. On or about April 7 and September 16, 1947, and March 9, 1948, the Denver Serum Co. shipped a number of bottles of Denhalant and a number of booklets entitled "Denver Serum Co. Veterinary Supplies" from Denver, Colo. On or about January 25 and April 1, 1948, the VioBin Corp. shipped a number of bottles of Rex wheat germ oil from Monticello, Ill.

PRODUCT: 176 1-pint bottles and 162 ½-pint bottles of Denhalant, 41 1-pound cans of Arsiden, 52 1-gallon bottles and 241 1-pint bottles of Dencolten, 35 1-pint bottles, 13 1-quart bottles, and 10 1-gallon cans of Rex wheat germ oil, and 112 booklets, at Mitchell, S. Dak.

Analyses showed that the *Denhalant* consisted essentially of approximately 70 percent of mineral oil and approximately 30 percent of a mixture of a turpentine oil, phenol (carbolic acid), guaiacol and/or creosote, and a minute proportion of iodine; that the *Arsiden* consisted chiefly of willow bark and 3 percent arsenic trioxide, with small proportions of potassium iodide, linseed meal, iron oxide, and sulfur; and that the *Dencolten* consisted of guaiacol, oil of eucalyptus, and creosote, in a mineral oil base. No analysis was made of the *Rex wheat germ oil*, and it was assumed that the product was as represented.

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the bottles and cans containing the products and statements appearing in the catalog shipped by the Denver Serum Co., and accompanying the articles, represented and suggested:

That the *Denhalant* would be effective in loosening mucous in the nose and throat of poultry when floated on the drinking water, and in treating colds and roup in poultry;

That the Arsiden would be effective as a treatment for poll evil, fistulous withers, and other chronic infections of horses and cattle, and as a tissue building tonic;

That the Dencolten was an effective aid in the treatment of simple colds, flu, bronchitis, and other diseases of the air passages of animals and poultry;

That the Rex wheat germ oil was effective as an aid in the prevention and treatment of sterility and breeding difficulties, in preventing abortion, and in increasing resistance to disease.

The above statements in the labeling of the articles were false and misleading since the articles would not be effective for the purposes represented and suggested.

DISPOSITION: February 1, 1949. The Denver Serum Co. having appeared as claimant for the products, Denhalant, Arsiden, and Dencolten, and the booklets entitled "Denver Serum Co. Veterinary Supplies," judgment of condemnation was entered against the claimed drugs, which were ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. None of the booklets had been seized, and action against the booklets subsequently was dismissed.

The VioBin Corp. appeared as claimant for the Rex wheat germ oil and filed an answer denying that the booklets shipped by the Denver Serum Co. constituted labeling of the product. However, on January 31, 1950, the VioBin Corp. having entered into a stipulation admitting that the Rex wheat germ oil was misbranded, judgment of condemnation was entered and the court ordered that the product be disposed of by the United States marshal. Accordingly, the product was destroyed.

3219. Misbranding of Gall-Vet. U. S. v. 99 Bottles, etc. (F. D. C. No. 29090. Sample No. 47666-K.)

LIBEL FILED: May 11, 1950, Eastern District of North Carolina.

ALLEGED SHIPMENT: On or about March 4 and December 9, 1949, by the Sal-Vet Mfg. Co., from Cleveland, Ohio.

PRODUCT: 99 2-ounce bottles and 54 8-ounce bottles of Gall-Vet at Wilson, N. C., together with a number of accompanying circulars entitled "Heal It With Gall Vet." Analysis showed that the product consisted of a water and alcohol solution of boric acid and methyl violet.

LABEL, IN PART: "Gall Vet * * * Contains 12% Medicated Alcohol Pyoktanin."

Nature of Charge: Misbranding, Section 502 (a), certain statements in the labeling of the article, which statements represented and suggested that the article was effective to restore flesh and skin to a healthy, normal condition, and to heal cuts and sores of any kind, anywhere, on any animal, were false and misleading since the article was not effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since "Medicated Alcohol" and "Pyoktanin" are not the common or usual names, respectively, for isopropyl alcohol and methyl violet.

Disposition: July 22, 1950. Default decree of condemnation and destruction.

3220. Misbranding of Foxcentrate, Fox No. 1 mineral feed, and Saturation feed. U. S. v. 67 Bags, etc. (F. D. C. No. 29040. Sample Nos. 76004-K to 76007-K, incl.)

LIBEL FILED: April 7, 1950, District of Minnesota.

ALLEGED SHIPMENT: On or about December 9, 1949, and January 27 and 31 and February 8 and 13, 1950, by Foxbilt, Inc., from Des Moines, Iowa.

PRODUCT: 103 100-pound bags of Foxcentrate, 25 100-pound bags of Fox No. 1 mineral feed, and 6 10-pound drums of Saturation feed, at Lewiston, Minn. Examination disclosed that the products were feed supplements.

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements in leaflets entitled "The Ideal Way to Feed Foxcentrate" and "Foxcentrate," which accompanied the Foxcentrate and the Fox No. 1 mineral feed, were false and misleading since these articles were not capable of accomplishing the results stated and implied. The statements represented and suggested that the articles would sweeten and alkalize the digestive system and reduce disturbances in the digestive processes of backward pigs; that the digestive system of swine is closed or obstructed and needs opening or freeing by use of the articles; and that swine frequently suffer from hyperacidity, and their digestive system needs alkalinization and could be rendered alkaline by administration of the alkaline substances contained in the article.

Further misbranding, Section 502 (a), certain statements in a leaflet entitled "Directions for Feeding," which accompanied the *Saturation feed*, were false and misleading. The statements represented and suggested that vitamin E, which the article contained, was essential for normal reproduction in cows, bulls, sows, boars, ewes, mares, and stallions, whereas vitamin E is not essential for normal reproduction in these animals.

Disposition: May 24, 1950. Foxbilt, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling under the supervision of the Federal Security Agency.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3201 TO 3220 PRODUCTS

N. J. No. | N. J. No. Alpha estradiol tablets_____ 3208 Estrogenic substance_____ 3208 Androgenic substance_____ 3208 Fox No. 1 mineral feed_____ 3220 Foxcentrate_____ 3220 Arsiden_____ 3218 3211 Arthritis, remedy for_____ Gall-Vet_____ 3219 Bandages_____ 3209 Glorion_____ 3215 Benadryl capsules_____ 3202 Hindu Magic liniment_____ 3213 Benzedrine Sulfate tablets__ 3202, 3203 Hollywood Vita-Rol device____ 3217 Cosmetic (subject to the drug pro-Imdrin_____ 3211 visions of the Act)_____ 3215 Liniment, Hindu Magic---- 3213 3218 Methyl testosterone tablets____ 3208 Dencolten____ Denhalant_____ 3218 Mineral feed, Fox No. 1_____ Devices_____ 3210, 3217 Nembutal Sodium capsules__ 3204, 3205 Dexedrine Sulfate tablets___ 3202-3204 Pep tonic_____ Dressings. See Bandages. Phenobarbital tablets_____ 3202, 3205 Estradiol, alpha, tablets_____ 3208 Procaine hydrochloride 2%____ 13201

^{1 (3201)} Contains opinion of the court.

N.	. J. No.	N. J. No.			
Prophylactics	3210	Testosterone, methyl, tablets 3208			
Raysol	3214	Tetter salve 3213			
Rex wheat germ oil	3218	Thyroid tablets 3204, 3205, 3212			
Rheumatism, remedy for	3211	Tonic, Pep 3213			
Salicyline No. 2 tablets	¹ 3201	Veterinary preparations 3218, 3220			
Salve, tetter	3213	Vitamin preparations 13201			
Saturation feed	3220	veterinary 3218, 3220			
Seconal Sodium capsules	3206	Vita-Rol device, Hollywood 3217			
Sulfathiazole tablets	3207	Wheat germ oil, Rex 3218			
Taj Quality tetter salve and Taj		Witch hazel 3216			
Superior balm	3213				
SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS					
N	. J. No.	N. J. No.			
Approved Products, Inc.:	. 0. 110.	Hugg The Druggist. See Hugg,			
witch hazel	3216	J. H.			
Baker, H. V.:	0220	Hugg's Drugs. See Hugg, L. R.			
sulfathiazole tablets	3207	Kalamazoo Pharmacal Co.:			
Baker's Cut Rate Drugs. See		thyroid tablets 3212			
Baker, H. V.		Kendall, C. B.:			
Beil, N. N.:		procaine hydrochloride 2% and			
methyl testosterone tablets and		Salicyline No. 2 tablets ¹ 3201			
alpha estradiol tablets	3208	Kendall, C. B., Co., Inc.:			
Dean Rubber Mfg. Co.:	0_00	procaine hydrochloride 2% and			
prophylactics	3210	Salicyline No. 2 tablets ¹ 3201			
Denver Serum Co.:		Miller, J. B. See Miller, John			
Denhalant, Arsiden, and Den-		Byron.			
colten	3218	Miller, John Byron:			
£ast & West Herbs Laboratory:		Seconal Sodium capsules 3206			
Pep tonic	3213	Monteith, R. E.:			
Fitzgerald, E. S.:		procaine hydrochloride 2% and			
Benadryl capsules, Benzedrine		Salicyline No. 2 tablets ¹ 3201			
Sulfate tablets, Dexedrine		Northrup, M. S.:			
Sulfate tablets, and pheno-		Nembutal Sodium capsules,			
barbital tablets	3202	phenobarbital tablets, and thyroid tablets 3205			
Fitzgerald Drug Store. See Fitz-		thyroid tablets 3205 Northrup Drug Store. See North-			
gerald, E. S.		rup, M. S.			
Foxbilt, Inc.:		Raysol Distributing Corp.:			
Foxcentrate, Fox No. 1 mineral	-	Raysol 3214			
feed, and Saturation feed	3220	Research Products. See Beil,			
Glorion Corp. of America:		N. N.			
Glorion	3215	Rhodes Pharmacal Co., Inc.:			
Hugg, J. H.:		Imdrin 3211			
Benzedrine Sulfate tablets and		S & D Engineering Co.:			
Dexedrine Sulfate tablets	3203	Hollywood Vita-Rol device 3217			
Hugg, L. R.:		Sal-Vet Mfg. Co.:			
Dexedrine Sulfate tablets,		Gall-Vet 3219			
Nembutal Sodium capsules,		Seamless Rubber Co.:			
and thyroid tablets	3204	adhesive bandages 3209			

^{1 (3201)} Contains opinion of the court.

N.	J. No.	N. J. No.
Sims Pharmacal Co.:		VioBin Corp.:
thyroid tablets	3212	
Taj Perfume Co.:		Windsor Chemical Laboratories.
Pep tonic, Taj Quality tetter		See Approved Products, Inc.
salve, Taj Superior balm, and		
Hindu Magic liniment	3213	

ERRATUM

D. D. N. J. No. 3181–3200: Change date of signature on p. 169 from September 30, 1950, to November 30, 1950.



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

U. S. GOVERNMENT PRINTING OFFICE: 1951

D. D. N. J., F. D. C. 3221-3240

Issued January 1951

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3221-3240

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs.

WASHINGTON, D. C.,

CONTENTS *

Page	Page
Drugs actionable because of poten-	Drugs and devices actionable be-
tial danger when used accord-	cause of deviation from official
ing to directions 208	or own standards 215
Drugs and devices actionable be-	Drugs and devices actionable be-
cause of failure to bear ade-	cause of false and misleading
quate directions or warning	claims216
statements210	Drugs for human use 216
Drug for veterinary use 214	Drugs for veterinary use 219
ing to directions	or own standards 215 Drugs and devices actionable because of false and misleading claims 216 Drugs for human use 216

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3223, 3224; omission of, or unsatisfactory, ingredients statements, Nos. 3222-3224, 3226, 3227, 3235, 3240; failure to comply with the packaging requirements of an official compendium, Nos. 3236; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3223, 3224, 3226, 3227, 3240; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3224, 3226, 3227, 3235; cosmetic, actionable under the drug provisions of the Act, No. 3227.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3221. Misbranding of Metandren Linguets and Neo-Hombreol tablets. U. S. v. United Research Laboratories, Inc., and Robert Roberts. Pleas of nolo contendere. Corporation fined \$75; individual, \$3. (F. D. C. No. 28119. Sample Nos. 12371-K, 12376-K, 47160-K.)

Information Filed: January 20, 1950, Eastern District of Pennsylvania, against United Research Laboratories, Inc., Philadelphia, Pa., and Robert Roberts, vice president of the corporation.

ALLEGED SHIPMENT: On or about April 22, June 17, and July 6, 1949, from the State of Pennsylvania into the States of New Jersey and West Virginia.

Product: Examination disclosed that the products consisted of methyl testosterone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Hormones and the Male Climacteric" were false and misleading. The statements represented and suggested that the articles would be adequate treatments for headache, excessive fatigue, nervousness irritability, insomnia, decreased memory and power of concentration, a feeling of uncertainty and tremulousness, vasomotor disturbances, such as flashes, sweats, chills, and parasthesias, vague pains, particularly in the region of the bladder, a loss of force in the urinary stream, clinical signs of prostatic hyperplasia or nonspecific prostatitis, decrease in libido and potency, symptoms of climacteric syndrome, and involutional melancholia; that the articles would prevent the "clock of life from running down"; and that they would permit the user to resume with confidence normal business and social activities. The articles would not be adequate treatments for the conditions represented; they would not prevent the "clock of life from running down"; and they would not permit the user to resume with confidence normal business and social activities.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration since each *Metandren Linguet* and *Neo-Hombreol tablet* contained 5 milligrams of methyl testosterone; and the labeling of the articles failed to warn that their use may result in sterility, and that their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

Further misbranding, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in their labeling. Each Metandren Linquet and Neo-Hombreol tablet contained 5 milligrams of methyl testosterone, and the use of articles containing 5 milligrams of methyl testosterone, i. e., in each Metandren Linguet and Neo-Hombreol tablet, with the frequency prescribed, recommended, and suggested in the labeling, namely, 3 to 4 Linguets (tablets) per day, would be dangerous to health since such use may result in sterility, and since their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: May 3, 1950. Pleas of nolo contendere having been entered, the court fined the corporation \$75 and the individual \$3.

3222. Misbranding of Special tablets and Oxylin antiseptic tablets. U. S. v. 5,000 Tablets, etc. (F. D. C. No. 29314. Sample No. 81007-K.)

LIBEL FILED: May 12, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 12, 1950, by D. M. Olmstead Laboratories, from Camden, N. J.

PRODUCT: 5,000 Special tablets in bulk, and 19 100-tablet bottles, 9 200-tablet bottles, 6 500-tablet bottles, and 7 1,000-tablet bottles of Oxylin antiseptic tablets, at Upper Darby, Pa.

Results of Investigation: The tablets contained in the bottles were found to have been repacked by Meredith L. Evons, Upper Darby, Pa., from the bulk shipment mentioned above.

LABEL, IN PART: (Bulk shipment) "Special Tablets * * * Each Tablet contains: Oxyquinoline sulfate 1.67 grs. Saccharine ½ gr. Oil Peppermint Oil Wintergreen Boric Acid q. s. 7.5 grs. C # 20650"; (repackaged tablets) "Oxylin Antiseptic Tablets * * * Each tablet contains 1.67 grains of oxyquinoline sulfate (chinosol), also saccharine, winter green and peppermint.

* * * Internal Uses:—Oxylin Tablets are a valuable intestinal and urinary antiseptic, inhibit bacteria, arrest fermentation and allay irritation. Prescribed internally wherever intestinal or urinary antisepsis is desired. Indicated conditions are hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhea (in solution for irrigation and orally), nephritis, pyelitis, cystitis, pyuria. Lauded as a specific for intestinal grippe, influenza and common cold. Dosage—Adults 3 tablets swallowed with water on an empty stomach, 3 or 4 times daily. In acute or stubborn cases, increase dosage to three tablets every two hours. Children, one tablet, four times daily, may be dissolved in water. Do not chew the tablets."

NATURE OF CHARGE: Misbranding (tablets in bulk), Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in such respect when introduced into, and while in, interstate commerce.

Misbranding (tablets in bottles), Section 502 (a), the label of the article contained statements which represented and suggested that the article was useful for intestinal or urinary antisepsis, and to arrest fermentation and allay irritation, and was an adequate treatment for hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dystentery, bed wetting, gonorrhea, nephritis, pyelitis, cystitis, pyuria, intestinal grippe, influenza, and the common cold, which statements were false and misleading since the article was not useful nor an adequate treatment for the conditions stated and implied; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, boric acid; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling. The article in the bottles was misbranded in the respects indicated while held for sale after shipment in interstate commerce.

DISPOSITION: June 20, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3223. Misbranding of Benzedrine Sulfate tablets, Seconal Sodium capsules, Sulfonamides Triplex tablets and Benadryl Hydrochloride capsules. U. S. v. Edwin L. Martin (Martin's Drug Store). Plea of nolo contendere. Defendant placed on probation for 1 year. (F. D. C. No. 26732. Sample Nos. 45577-K to 45580-K, incl., 45969-K, 45970-K, 45973-K, 46181-K.)

Information Filed: September 26, 1949, Western District of Arkansas against Edwin L. Martin, trading as Martin's Drug Store, Hot Springs, Ark.

INTERSTATE SHIPMENT: Between the approximate dates of May 12 and December 20, 1948, from the States of Missouri, Indiana, and Pennsylvania, into the State of Arkansas.

ALLEGED VIOLATION: On or about December 28, 1948, and February 4, 5, and 12, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be removed from the bottles in which they had been shipped, and to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE of CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs bore no directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium was a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged Sulfonamides Triplex tablets were fabricated from two or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, namely sulfathiazole, sulfadiazine, and sulfamerazine; and, Section 502 (f) (2), the repackaged Sulfonamides Triplex tablets bore no labeling containing adequate warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: October 3, 1949. A plea of nolo contendere having been entered, the court placed the defendant on probation for 1 year.

3224. Misbranding of thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules. U. S. v. William G. Neu. Plea of guilty. Fine, \$1,000. (F. D. C. No. 29434. Sample Nos. 60942-K to 60945-K, incl., 60948-K, 60949-K.)

Information Filed: July 25, 1950, Eastern District of Missouri, against William G. Neu, a pharmacist for Neels Drugs, St. Louis, Mo.

INTERSTATE SHIPMENT: From the States of Michigan, Pennsylvania, Indiana, and New York, into the State of Missouri, of quantities of thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules.

^{*}See also Nos. 3221, 3222.

NATURE OF CHARGE: While the thyroid tablets were being held for sale at Neels Drugs after shipment in interstate commerce, William G. Neu, on or about August 17, 1949, caused a number of these tablets to be sold and disposed of, in the original bottles in which the tablets had been shipped in interstate commerce, without requiring a prescription of a physician. When received by the defendant, the label of the tablets bore the statement "Warning—To be dispensed only by or on the prescription of a physician," and as a result, the tablets were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling. However, by selling the tablets without a prescription, the defendant caused the exemption to expire, resulting in the misbranding of the thyroid tablets in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

In addition to the above sale, the defendant, on or about August 15 and 17, 1949, caused various quantities of thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules to be repackaged and sold without a prescription while they were being held for sale at Neels Drugs after shipment in interstate commerce, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1), the repackaged drugs, other than the diethylstilbestrol tablets, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and when repackaged they failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged Benzedrine Sulfate tablets failed to bear a label containing the common or usual name of the tablets; Section 502 (e) (2), the repackaged Sulfonamides Triplex tablets were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient, namely, sulfamerazine, sulfadiazine, and sulfathiazole; Section 502 (f) (1), the labeling of all of the repackaged drugs, with the exception of the Sulfonamides Triplex tablets, failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged Sulfonamides Triplex tablets and the diethylstilbestrol tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: August 18, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,000.

3225. Misbranding of gelatin capsules and Newallium oleum capsules. U. S. v. 4 Cartons, etc. (F. D. C. No. 29392. Sample No. 81191-K.)

LIBEL FILED: July 10, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 14, 1949, by the Curtiss Candy Co., from Chicago, Ill.

PRODUCT: 4 cartons, each containing 10,000 capsules, and 144 100-capsule boxes, 72 50-capsule boxes, and 24 25-capsule boxes, of Newallium oleum capsules at Philadelphia, Pa., together with a number of folders entitled "Newallium Oleum" and "New Potent Antibiotic Reported in Garlic Newallium Oleum."

Analysis showed that the capsules contained a fatty oil, other than olive oil, and material derived from garlic.

RESULTS OF INVESTIGATION: The 4 cartons of the *gelatin capsules* were the remainder of an original shipment consisting of 10 cartons. After the receipt of such cartons by the consignee, R. M. Newcomb, Philadelphia, Pa., a number of the capsules were repackaged into the boxes described above. Information obtained at the time of the investigation indicated that the folders described above were printed in Philadelphia, Pa.

Label, in Part: (Cartons) "Quantity: 10,000 Size: 6 minim Soluble gelatin capsules each containing .344 gram fill garlic and vegetable oils. Dosage: 2 capsules daily. * * * W. G. Peacock Co. Evanston * * * Illinois"; (boxes) "Newallium Oleum * * * 6-Minim Capsules Concentrate of valuable factors in garlic infused in Olive Oil. * * * One capsule twice daily with meals, or as directed by doctor. R. M. Newcomb Co. 5231 Chestnut St. Philadelphia 39, Pa."

Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the article in the cartons failed to bear adequate directions for use. The article was misbranded in such respect when introduced into, and while in, interstate commerce.

Misbranding, Section 502 (a), the folders accompanying the article contained statements which represented and suggested that the article contained in the cartons and in the boxes was an adequate and effective treatment for high blood pressure, respiratory and intestinal catarrh, colitis, enteritis, diarrhea, and related ailments; that the article was a vermifuge for children or adults; that it would prevent and cure infections; that it was a bactericide when employed in the recommended dosage; that it would relieve headache and dizziness associated with high blood pressure; that it was an effective treatment for chronic enterocolitis, Salmonella infections, including paratyphoid; and that it was a kidney stimulant. The statements were false and misleading since the article was not an adequate and effective treatment for such conditions, and would not fulfill the other promises of benefit stated and implied; and the statement "Concentrate of valuable factors in garlic infused in Olive Oil" borne on the label of the article in the boxes was false and misleading since the article did not have the composition stated. The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce.

Disposition: July 26, 1950. R. M. Newcomb having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3226. Misbranding of Syno. U. S. v. 3 Bottles, etc. (F. D. C. No. 29014. Sample Nos. 59939-K, 59940-K.)

LIBEL FILED: March 21, 1950, Eastern District of Wisconsin.

Alleged Shipment: On or about October 12, 1948, by Hubert H. Setzler, from Newberry, S. C.

PRODUCT: 3 full and 1 partially filled 1-gallon bottles and 67 2-fluid-dram bottles of Syno at Milwaukee, Wis., in possession of Syno Sales, Inc. The 2-fluid-dram bottles were filled with the product which was taken from part of the October 12 shipment.

Examination of samples showed that the product consisted essentially of chloroform, approximately 40 percent by volume, camphor, alcohol, water, a fatty oil, and a small proportion of free fatty acid.

LABEL, IN PART: (Gallon bottle) "Syno." Some of the small bottles were unlabeled; others were labeled in part: (carton) "Syno Contains: Olive Oil, Camphor Monoethylene, Camphor Dicarbontrichloride, Palmotolic Acid, Chloroform 6% and Alcohol 5% * * * For Painful Sinusitis."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Syno" appearing on the label was false and misleading since the name suggested and implied that the article was effective in the treatment of sinusitis; Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the quantity or proportion of chloroform contained in the article; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in the above respects when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (a), the statement "Contains * * * Chloroform 6% appearing on the label of the article, which had been repacked into small bottles, was false and misleading since the article contained more than 6 percent of chloroform; the statement "Contains * * * Camphor Monoethylene, Camphor Dicarbontrichloride" appearing on the carton and bottle labels of the repacked article was false and misleading since the article did not contain such ingredients; and certain statements in the labeling of the repacked article were false and misleading since the statements represented and suggested that the article was adequate and effective in the treatment of sinusitis, whereas the article was not adequate and effective in the treatment of sinusitis. The repacked article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 29, 1950. Default decree of condemnation and destruction

3227. Misbranding of hair conditioner. U. S. v. 283 Jars, etc. (F. D. C. No. 29041. Sample No. 1745-K.)

LIBEL FILED: On or about April 13, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about February 10 and 17, 1950, by Argyle Laboratories, Inc., from New York, N. Y.

PRODUCT: Hair conditioner. 283 16-ounce jars and 301 8-ounce jars at St. Petersburg, Fla., in possession of Miss Peggy Rohrer, trading as the Tru-Lan Co.

RESULTS OF INVESTIGATION: The product was shipped unlabeled. After its receipt, the consignee, Miss Peggy Rohrer, caused to be affixed to some of the jars a label reading, in part: "Tru-Lan Hair Conditioner With Lanolin." No labeling agreement existed between the shipper and the consignee.

Examination showed that the product consisted essentially of petrolatum, lanolin, water, and perfume.

Nature of Charge: Misbranding (unlabeled bottles), Sections 502 (b) (1) and (2), the product failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the product was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), its labeling failed

to bear adequate directions for use. The product was misbranded in the above respects when introduced into, and while in, interstate commerce.

Misbranding (labeled bottles), Section 502 (a), the statement which appeared on the label "To Help Relieve: Excessive Falling Hair... Itching Scalp * * * Various Scalp Ills" was false and misleading since the product was not an effective treatment for such conditions.

Further misbranding, Section 502 (a), the label statement "With Lanolin" was misleading since the product also contained petrolatum; and, Section 502 (e) (2), the product was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. The product was misbranded in the latter respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 16, 1950. Default decree of condemnation and destruction.

3228. Misbranding of X-ray machine. U. S. v. 1 X-ray Machine, etc. (F. D. C. No. 25820. Sample No. 3145–K.)

LIBEL FILED: October 12, 1948, District of Maryland.

ALLEGED SHIPMENT: On or about May 14 and June 17, 1947, by the Westinghouse Electric Corp., from Omaha, Nebr.

PRODUCT: 1 X-ray machine with accessories at Baltimore, Md.

Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in that the labeling failed to state the conditions for which it was to be used.

Disposition: April 25, 1949. Virginia Laboratories, Inc., Baltimore, Md., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be delivered to the claimant, under bond, to be sold or disposed of for uses which conform with the requirements of the law, under the supervision of the Food and Drug Administration. On June 30, 1950, the device was sold to a physician specializing in dermatology, for use in his practice.

DRUG FOR VETERINARY USE

3229. Misbranding of phenothiazine drench. U. S. v. 1 Drum * * *. (F. D. C. No. 29489. Sample No. 69913-K.)

LIBEL FILED: July 14, 1950, District of Kansas.

ALLEGED SHIPMENT: On or about February 16, 1950, by the Pearson-Ferguson Chemical Co., from Kansas City, Mo.

Product: 1 150-pound drum of phenothiazine drench at Lyndon, Kans. Examination showed that the product was powdered phenothiazine.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since no directions for use appeared therein; and, Section 502 (f) (2), the labeling failed to warn against use of the article in the treatment of sick, feverish, or physically weak animals, especially horses, since such animals should not be treated with the article except on the advice of a veterinarian.

DISPOSITION: September 26, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3230. Adulteration of chorionic gonadotropin. U. S. v. 116 Vials * * *. (F. D. C. No. 29355. Sample No. 74597-K.)

LIBEL FILED: June 7, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 26 and March 2 and 8, 1950, from Orange, N. J.

PRODUCT: 116 vials of chorionic gonadotropin at Woodside, Long Island, N. Y.

Label, IN Part: (Vial) "Multiple Dose 10cc Vial Chorionic Gonadotropin 10,000 I. U."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 10,000 International Units of *chorionic gonadotropin*. The article was adulterated while held for sale after shipment in interstate commerce.

Disposition: August 11, 1950. Default decree of condemnation and destruction.

3231. Adulteration and misbranding of Bantex cohesive gauze bandages. U. S. v. 38 Boxes * * *. (F. D. C. No. 29405. Sample No. 71324-K.)

Libel Filed: July 20, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about May 15, 1950, by Brasel Products, Inc., from Batavia, Ill.

PRODUCT: 38 boxes of Bantex cohesive gauze bandages at Los Angeles, Calif.

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with micro-organisms. Statements in the labeling such as "Bantex Cohesive Gauze may be used instead of plain gauze" and "this gives the wound adequate protection" imply that the article was sterile and therefore suitable for such uses.

Label, in Part: (Box) "Bantex Cohesive Gauze Bandage 10 Yard Rolls Totaling 12" of Width 12-1."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), a statement in an accompanying leaflet entitled "Bantex Cohesive Gauze Bandage" was false and misleading since it represented and suggested that the article was effective in the treatment and relief of varicose veins and sprains, whereas it was not effective in the treatment of varicose veins and sprains.

DISPOSITION: August 8, 1950. Default decree of condemnation and destruction.

3232. Adulteration of prophylactics. U. S. v. Klingfast Rubber Co. and Clyde W. Martin. Pleas of guilty. Corporation fined \$1,000 and individual defendant \$200, plus costs. (F. D. C. No. 29437. Sample Nos. 1144-K, 63849-K, 63850-K, 63853-K.)

Information Filed: July 7, 1950, Northern District of Ohio, against the Klingfast Rubber Co., a corporation, Akron, Ohio, and Clyde W. Martin, president of the corporation.

ALLEGED SHIPMENT: On or about October 13, 1948, and June 9 and 15 and November 1, 1949, from the State of Ohio into the State of Georgia.

NATURE of CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess since it pur-

- ported to be a prophylactic, but it was ineffective for prophylaxis because of the presence of holes.
- DISPOSITION: October 4, 1950. Pleas of guilty having been entered, the court fined the corporation \$1,000 and the individual defendant \$200, plus costs.
- 3233. Adulteration of prophylactics. U. S. v. John M. Adams (Klingfast Sales Co.). Plea of nolo contendere. Fine of \$300 or imprisonment for 1 year. (F. D. C. No. 29436. Sample Nos. 52359-K, 52364-K.)
- Information Filed: On July 6, 1950, Northern District of Georgia, against John M. Adams, trading as the Klingfast Sales Co., Atlanta, Ga.
- ALLEGED SHIPMENT: On or about November 16 and December 7, 1949, from the State of Georgia into the State of Tennessee.
- Label, in Part: "Klintab Caps * * * A Cap Type Rubber Glans Sheath * * * Manufacturer Klingfast Rubber Co. Akron, Ohio."
- Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. The article purported and was represented to be a prophylactic, whereas it was not a prophylactic, but was ineffective for prophylaxis because of the presence of holes.
- DISPOSITION: August 28, 1950. A plea of nolo contendere having been entered, the court sentenced the defendant to pay a fine of \$300 or to serve 1 year in jail.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

- 3234. Misbranding of Raysol. U. S. v. 9 Bottles * * * (F. D. C. No. 27783. Sample No. 47595–K.)
- LIBEL FILED: August 22, 1949, District of Columbia.
- ALLEGED SHIPMENT: On or about May 16, 1949, from Kitchener, Ontario, Canada, to Prince Frederick, Md., and from the latter point into the District of Columbia.
- Product: 9 6-ounce bottles of Raysol at Washington, D. C. Examination showed that the product consisted of a water solution of calcium chloride, magnesium chloride, sodium chloride, and small amounts of other mineral salts, including potassium, iron, and iodine compounds.
- Label, in Part: "Raysol * * * The Raysol Co. P. O. Box 4335 Washington, D. C."
- Nature of Charge: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Raysol * * * The Raysol Company P. O. Box 4335. Washington, D. C." were false and misleading. The statements represented and suggested that the article was effective in the treatment of diabetes, anemia, angina pectoris, circulatory disorders, stomach ailments, kidney and bladder trouble, high blood pressure, arthritic and rheumatic pains, stomach ulcers, and ill health associated with a depletion of the minerals in the blood; and that the article would be effective for revitalizing the blood and for serving as a "Great, God-given Remedy." The article was not effec-

^{*}See also Nos. 3221, 3222, 3225-3227, 3231.

tive for such purposes. It was misbranded while held for sale after shipment in interstate commerce.

Disposition: September 12, 1950. Default decree of condemnation and destruction.

3235. Misbranding of Dr. Morse's Indian Root pills. U. S. v. 125 Dozen Bottles

* * * (F. D. C. No. 29343. Sample No. 38870-K.)

LIBEL FILED: June 6, 1950, District of Puerto Rico.

ALLEGED SHIPMENT: On or about February 21, 1950, by the W. H. Comstock Co., from Morristown, N. Y.

PRODUCT: 125 dozen bottles of *Dr. Morse's Indian Root pills* at Santurce, P. R. A circular entitled "Un Medicamento Casero De Confianza" was attached to each bottle of the product by means of a paper wrapper entitled "Raiz India Del Dr. Morse."

Analysis showed that the product consisted of plant drugs, including aloe.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the Spanish language in the circular accompanying the article were false and misleading since the article was not capable of fulfilling the promises of benefits stated and implied. The statements represented and suggested that the article would correct derangement of the digestive organs caused by overeating and overdrinking, and conditions resulting from disordered stomach and liver; that it was not merely a laxative but exerted an effect on the liver and, indirectly, on the entire system; that it was effective for imperfect digestion and disordered or sluggish liver; that it would keep the bowels regular and thereby remedy or prevent many disease conditions, including unnatural irritation of the mucous membrane of the intestines; that it would enable intestines that have lost their strength to perform their functions, would prevent inflammation, and would remedy 1,000 other complaints which otherwise would cause one a miserable and wretched life; that it would cleanse the stomach and bowels and restore their natural strength; that it would remedy biliousness and accompanying depression and demoralization of the entire system; that it would correct a feeling of heaviness, lack of energy, sick headache, etc., resulting from biliousness; that it would cause elimination of the bowel content in a natural way, establish a more healthy condition, and thus prevent and correct clogging of the ducts which connect the gall bladder with the liver and intestines, which may cause a backing up of bile, dull pains, uneasiness in the right side and shoulder blade, bitter taste, sudden dizziness on rising. spots before the eyes, coated tongue, looseness of bowels, and constipation on alternate days, rendering life hardly worth living; that it would relieve the primary cause of many of the most serious diseases; that it would restore the bowels to healthy action; that it would banish headache due to any of the conditions previously mentioned; that it would cleanse the stomach; and that it would relieve severe suffering of children from 1 day to 4 months of age.

Further misbranding, Section 502 (b) (1), the label attached to the immediate container of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; and Section 502 (e) (2), the article was fabricated from two or more ingredients, and the label attached to the immediate container of the article failed to bear a declaration of the active ingredients.

DISPOSITION: July 24, 1950. Default decree of condemnation and destruction.

3236. Misbranding of adhesive compresses. U. S. v. 16 Boxes * * *. (F. D. C. No. 29089. Sample No. 50850-K.)

LIBEL FILED: May 3, 1950, Western District of Washington.

Alleged Shipment: On or about October 31, 1949, from Los Angeles, Calif.

PRODUCT: 16 boxes of adhesive compresses at Seattle, Wash., in possession of the Safety & Supply Co.

RESULTS OF INVESTIGATION: The product was unlabeled when shipped, and the labels borne on the boxes at the time of seizure were those affixed by the consignee. The product consisted of an absorbent gauze compress affixed to a strip of film, the ends of which were coated with an adhesive composition.

At the time of the examination, the product was contaminated with viable micro-organisms.

Label, IN Part: (Box) "100 Transparent Clear First Aid Bands Adhesive Compresses Pkgd By Safety & Supply Co., Seattle, Wash."

NATURE of CHARGE: Misbranding, Section 502 (a), the label statement "First Aid" was false and misleading since the article was not sterile and thereby was not suitable for first aid; and, Section 502 (g), the article purported to be and was represented as "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and it was not packaged as prescribed therein since the units were not individually wrapped. The compendium provides that "Each Adhesive Absorbent Gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container." The article was misbranded while held for sale after shipment in interstate commerce.

Disposition: September 11, 1950. Default decree of condemnation and destruction.

3237. Misbranding of vacuum stimulator. U. S. v. Arthur T. Ricard (Ricard Mfg. Co.). Plea of guilty. Fine, \$30. (F. D. C. No. 24279. Sample Nos. 19222–K, 22336–K, 30051–K.)

Information Filed: November 22, 1948, District of Nebraska, against Arthur T. Ricard, trading as the Ricard Mfg. Co., Omaha, Nebr.

ALLEGED SHIPMENT: On or about September 7 and 10 and October 14, 1947, from the State of Nebraska into the States of Ohio, Texas, and Arizona.

PRODUCT: Examination showed that the device consisted of a clear plastic cylinder attached to a hand-propelled vacuum pump.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars and instruction sheets headed "If You Are Young and Robust, 'Full of Pep'" and "Instructions For Using Our Vacuum Stimulator To The Male Organ" were false and misleading. The statements represented and suggested that the device would enable one to become mentally fit and able-bodied; that it would restore vitality, pep, ambition, and one's zest for life; that it would be efficacious in the treatment of nervousness, poor memory, lack of appetite, and stomach trouble, and in the treatment of an enlarged, inflamed, or faulty prostate gland, weak or lame back muscles, and leg or pelvic pains; that it would be efficacious in the cure, mitigation, and treatment of insomnia, poor blood condition, blood deficiencies, enlarged and hardened condition of the prostate gland, hot heaviness and aching depression in the region of the rectum, acute pains in the rectal region and in the sciatic nerves, pres-

sure on the neck of the bladder, cystitis, urethritis, calculus, and cloudy urine containing particles of shreds and mucus; that the device would enable one to enjoy a fuller, richer, and better physical existence, to become a more powerful and better man, and to sleep through the night without having to get out of bed; that it would quicken the mental powers, improve the memory, relieve depressing pressure on the nerves, and render the prostate gland and sexual tissues full of action and new life; that it would restore lost vigor and vitality and increase the vitality of men 70 and 80 to that of men 45 or 50; that it would have an energizing effect on the cells of the brain; that it would strengthen and revitalize worn-out bodies and prevent brain fag and nervous breakdown; that it would enable users to feel like "new men"; that it would keep old age away; and that it would build up the prostate gland and sexual tissues. The device would not fulfill the promises of benefit stated and implied.

Disposition: October 17, 1950. A plea of guilty having been entered, the court imposed a fine of \$30.

3238. Misbranding of Multiple Pin-Hole spectacles. U. S. v. 340 Devices, etc. (F. D. C. No. 29394. Sample Nos. 71508–K, 71550–K.)

LIBEL FILED: July 17, 1950, Southern District of California.

ALLEGED SHIPMENT: A number of the articles were shipped from New York, N. Y., between the approximate dates of June 5 and 29, 1950, and the remainder were shipped from New York, N. Y., at various times in 1948 and 1949.

PRODUCT: 586 Multiple Pin-Hole spectacles at Glendale, Calif., together with accompanying printed matter consisting of circulars entitled "Price \$18.50 Multiple Pin-Hole Spectacles," copies of a reprint from the Glendale News Press, copies of 2 testimonial letters dated July 29, 1948, and January 20, 1950, and folders entitled "The Greeks Had a Word for It."

The devices consisted of plastic spectacles, with rows of small holes through the lenses.

RESULTS OF INVESTIGATION: The accompanying printed matter was printed locally for the consignee and was sent through the mails to persons requesting information about the device.

LABEL, IN PART: "Visual Aid."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling which represented and suggested that the device was adequate and effective in the cure and elimination of the causes of defective vision were false and misleading since the device was not adequate and effective in the cure and elimination of the causes of defective vision. The device was misbranded while held for sale after shipment in interstate commerce.

Disposition: September 21, 1950. Sunset Laboratories, Inc., Glendale, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the article be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3239. Misbranding of Blake's Mineral Compound. U. S. v. 27 Packages, etc. (F. D. C. No. 29321. Sample No. 78621-K.)

LIBEL FILED: May 19, 1950, District of Montana.

ALLEGED SHIPMENT: On or about July 22 and August 20, 1948, by the Hy-Life Mineral Co., from Denver, Colo.

Product: 27 packages, each containing 3½ pounds, of Blake's Mineral Compound at Belgrade, Mont., together with an accompanying pamphlet entitled "Feed Blake's Mineral Compound."

LABEL, IN PART: "Blake's Mineral Compound * * * Ingredients: (active)
Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the package label and in the accompanying pamphlet were false and misleading since the article when used as directed was not effective for the purposes represented. The statements represented and suggested that the article when used as directed was effective in the prevention and treatment of livestock from the effects of poisonous weeds and from bloat while pasturing on green alfalfa or clover or in corn or wheat fields.

DISPOSITION: July 13, 1950. Default decree of condemnation and destruction.

3240. Misbranding of Chick Tone and Pig and Hog Tone. U. S. v. 23 Packages, etc. (F. D. C. No. 29337. Sample Nos. 72907–K, 72908–K.)

LIBEL FILED: May 31, 1950, Southern District of Indiana.

ALLEGED SHIPMENT: On or about April 13, 1950, by the Cumberland Poultry Supply Co., from Nashville, Tenn.

PRODUCT: 23 packages of Chick Tone and 23 packages of Pig and Hog Tone at Birdseye, Ind.

Analysis showed that the *Chick Tone* consisted essentially of hydrated lime (80 percent), epsom salt (14 percent), soda, iron compounds, sulfur, salt, nux vomica (0.4 percent), and quassia. The amount of strychnine (a constituent of nux vomica) in the *Chick Tone* was approximately 0.02 gram, and the quantity of the contents of the package of the product was approximately 1 pound.

Analysis showed that the *Pig and Hog Tone* consisted essentially of hydrated lime (71 percent), epsom salt (11 percent), soda (10 percent), an iron compound, nux vomica, quassia, salt, and sulfur. It contained no significant proportions of sodium fluoride, nicotine, rock phosphate, or calcium phosphate. The amount of strychnine present as a constituent of nux vomica was approximately 0.1 gram, and the quantity of the contents of the package was 1 pound and 1½ ounces.

Nature of Charge: Chick Tone. Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective for the purposes stated and implied; the article contained less than the stated amount of strychnine and contained no significant proportion, if any, of calcium phosphate; and it would not supply all the mineral elements needed by poultry as represented: "* * * Tone * * * To Preserve and Promote the Health of Poultry and Aids in Egg Production Chick Tone is made from a combination of ingredients correctly balanced to act as a tonic and laxative and is particularly valuable to the moulting flock, the growing chick, and the heavy egg producer. Aids In The Treatment For Worms, Gapes, Roup, White Diarrhoea, And Helps Keep The Poultry In A Healthy Condition The consistent use of Chick Tone is highly recommended as a preventive and treatment for Range Paralysis * * * For best results Chick Tone should be used continuously as a regular tonic, conditioner * * * No additional minerals or salts required when Chick Tone is used regularly. * * * Ingredients—Nux Vomica, approx. 3.52 grams of Strychnine, Quassia, Epsom Salts, Red Oxide of Iron, Soda, Copperas, Sulphur Flour, Calcium Phosphate, Hydrated Lime, Salt" and "No additional minerals or salts required when Chick Tone is used regularly." Further misbranding, Section 502 (b) (2), the label of the article failed to bear an accurate statement of the quantity of the contents since the label statement "Contents: 1 Pound 4 ounces" was inaccurate; and, Section 502 (e) (2), the label of the article failed to bear a statement of the quantity or proportion of strychnine contained therein.

Pig and Hog Tone. Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective for the purposes stated and implied; the article contained less than the stated amount of strychnine and contained no significant proportion, if any, of sodium fluoride, nicotine, rock phosphate, or calcium phosphate; and it contained epsom salt, which was not declared as an ingredient: "* * Tone 'Removes The Cause' Pig and Hog Tone is compounded from a combination of ingredients that will thoroughly expel or dissolve all worms. It is a very effective treatment and preventative of cholera and other common diseases among hogs. Pig and Hog Tone builds stronger, bigger bones—is a mild laxative, increases appetite and keeps hogs in a thoroughly healthy condition, thereby promoting faster growth, more pounds, and is a guaranteed feed saver * * * In stubborn cases with old hogs, double the dose * * * Guaranteed Analysis Nux Vomica, appro. 3.52 grams Strychnine, Quassia, Sodium Floride, Red Oxide of Iron, Nicotine, Rock Phosphate, Sodium Chloride, Sulphate of Iron, Calcium Phosphate." Further misbranding, Section 502 (b) (2), the label of the article failed to bear a statement of the quantity of the contents; and, Section 502 (e) (2), the label of the article failed to bear a statement of the quantity or proportion of strychnine contained therein.

DISPOSITION: August 9, 1950. Default decree of forfeiture and destruction.

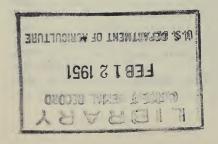
INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3221 TO 3240

PRODUCTS

N. J	J. No.	N. J. No.
Adhesive compresses	3236	Newallium oleum capsules 3225
Bandages and dressings 3231,	3236	Oleum, Newallium, capsules 3225
Bantex cohesive gauze bandages_	3231	Oxylin antiseptic tablets 3222
Benadryl hydrochloride capsules_	3223	Pentobarbital sodium capsules 3224
Benzedrine Sulfate tablets 3223,	3224	Phenothiazine drench 3229
Blake's Mineral Compound	3239	Pig and Hog Tone 3240
Chick Tone	3240	Pin-Hole spectacles, Multiple 3238
Chorionic gonadotropin	3230	Prophylactics 3232, 3233
Cosmetic (subject to the drug		Raysol 3234
provisions of the Act)	3227	Seconal Sodium capsules 3223
Devices 3228, 3232, 3233, 3237,	3238	Sinusitis, remedy for 3226
Diethylstilbestrol tablets	3224	Special tablets 3222
Dressings. See Bandages and		Spectacles, Multiple Pin-Hole 3238
dressings.		Stimulator, vacuum 3237
Gelatin capsules	3225	Sulfonamides Triplex tablets 3223,
Gonadotropin, chorionic	3230	3224
Hair and scalp preparation	3227	Syno 3226
Indian root bills, Dr. Morse's	3235	Thyroid tablets 3224
Metandren Linguets	3221	Tru-Lan hair conditioner 3227
Mineral Compound, Blake's	3239	Vacuum stimulator 3237
Morse's, Dr., Indian root pills	3235	Veterinary preparations 3229,
	3238	3239, 3240
Neo-Hombreol tablets	3221	X-ray machine3228

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

Adams, J. M.:	. J. No.	Neu, W. G.—Continued N.	J. No.
prophylactics	3233	bestrol tablets, and pento-	
Argyle Laboratories, Inc.:		barbital sodium capsules	3224
hair conditioner	3227	Newcomb, R. M.:	
Brasel Products, Inc.:		Newallium oleum capsules	3225
Bantex cohesive gauze band-		Newcomb, R. M., Co.:	
ages	3231	Newallium oleum capsules	3225
Comstock, W. H., Co.:		Olmstead, D. M., Laboratories:	
Dr. Morse's Indian root pills_	3235	Special tablets and Oxylin anti-	
Cumberland Poultry Supply Co.:		septic tablets	3222
Chick Tone and Pig and Hog		Peacock, W. G., Co.:	
Tone	3240	gelatin capsules	3225
Curtiss Candy Co.:		Pearson-Ferguson Chemical Co.:	
gelatin capsules and Newallium		phenothiazine drench	3229
oleum capsules	3225	Raysol Co.:	
Evons, M. L.:		Raysol	3234
Special tablets and Oxylin		Ricard, A. T.:	
antiseptic tablets	3222	vacuum stimulator	3237
Hy-Life Mineral Co.:		Ricard Mfg. Co. See Ricard,	
Blake's Mineral Compound	3239	А. Т.	
Klingfast Rubber Co.:		Roberts, Robert:	
prophylactics 3232	2, 3233	Metandren Linguets and Neo-	
Klingfast Sales Co. See Adams,		Hombreol tablets	3221
J. M.		Rohrer, Peggy, Miss:	
Martin, C. W.:		hair conditioner	3227
prophylactics	3232	Safety & Supply Co.:	
Martin, E. L.:		adhesive compresses	3236
Benzedrine Sulfate tablets,		Setzler, H. H.:	0_00
Seconal Sodium capsules,		Syno	3226
Sulfonamides Triplex tablets,		Syno Sales, Inc.:	00
and Benadryl Hydrochloride		Syno	3226
capsules	3223	Tru-Lan Co. See Rohrer, Peggy,	00
Martin's Drug Store. See Mar-	0220	Miss.	
tin, E. L.		United Research Laboratories,	
Neels Drugs. See Neu, W. G.		Inc.:	
Neu, W. G.:		Metandren Linguets and Neo-	
thyroid tablets, Benzedrine		Hombreol tablets	3221
Sulfate tablets, Sulfonamides	18	Westinghouse Electic Corp.:	J1.
Triplex tablets, diethylstil-	1	X-ray machine	3228
zapick dubicts, diethylatif		ar and muchine	0



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3241-3260

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

Paul B. Dunbar, Commissioner of Food and Drugs. Washington, D. C., January 25, 1951.

CONTENTS*

Pag	Pag
Drugs actionable because of failure	Drugs and devices actionable be-
to bear adequate directions or	cause of false and misleading
warning statements 22	4 claims23
Drug actionable because of con-	Drugs for human use 23
tamination with filth 22	8 Drugs for veterinary use 23
Drugs and devices actionable be-	Index23
cause of deviation from official	
or own standards 22	9

*For presence of a habit-forming narcotic without warning statement, see Nos. 3241, 3245, 3246; omission of, or unsatisfactory, ingredients statements, Nos. 3242, 3243, 3246, 3258; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3241-3248; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3241-3245, 3248.

922417---51



223

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3241. Misbranding of sulfathiazole lozenges, Dexedrine Sulfate tablets, and Tuinal capsules. U S. v. Elias A. Doerr (Doerr's Drug Store), and Arthur R. Morgan. Pleas of guilty. Each defendant fined \$100 and placed on probation for 1 year. (F. D. C. No. 2§121. Sample Nos. 61307-K, 61312-K, 61315-K, 61316-K.)
- INFORMATION FILED: January 31, 1950, Eastern District of Illinois, against Elias A. Doerr, trading as Doerr's Drug Store, Murphysboro, Ill., and Arthur R. Morgan, a pharmacist.
- INTERSTATE SHIPMENT: On or about December 10, 1947, and April 21 and May 27, 1949, from the States of Indiana and Missouri into the State of Illinois, of quantities of sulfathiazole lozenges, Dexedrine Sulfate tablets, and Tuinal capsules.
- ALLEGED VIOLATION: On or about July 22 and 27, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants, Elias A. Doerr and Arthur R. Morgan, caused a number of sulfathiazole lozenges and a number of Dexedrine Sulfate tablets to be repackaged and sold without a prescription, and on July 28, 1949, defendant Elias A. Doerr caused a number of sulfathiazole lozenges and a number of Tuinal capsules to be repackaged and sold without a prescription, which acts of the defendants resulted in the drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (1), one sale of the repackaged sulfathiazole lozenges failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Tuinal capsules* contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated as, habit forming; and when repackaged, the *Tuinal capsules* failed to bear a label containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), all of the repackaged drugs failed to bear labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: September 25, 1950. Pleas of guilty having been entered, the court fined each defendant \$100 and placed each on probation for 1 year.
- 3242. Misbranding of sulfathiazole tablets. U. S. v. Stephen S. Titus (Titus Pharmacy). Plea of guilty. Fine, \$600. (F. D. C. No. 29415. Sample Nos. 13614–K, 13619–K, 13805–K.)
- Information Filed: June 29, 1950, Eastern District of Pennsylvania, against Stephen S. Titus, trading as Titus Pharmacy, Philadelphia, Pa.
- INTERSTATE SHIPMENT: On or about September 10, 1948, from the State of New York into the State of Pennsylvania, of a quantity of sulfathiazole tablets.

ALLEGED VIOLATION: On or about July 15 and August 2 and 10, 1949, while a number of the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and Section 502 (e) (1), the label of the repackaged tablets failed to bear the common or usual name of the drug, namely, sulfathiazole.

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the labeling of the tablets involved in one of the sales bore no directions for use and since the directions, "2-1/4 x a day" and "2-1 Every 4 hours," borne on the labeling of the tablets involved in the other sales, were not adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: October 9, 1950. A plea of guilty having been entered, the court imposed a fine of \$600.

3243. Misbranding of sulfathiazole tablets. U. S. v. Jacob Sheckter (Sheckter's Drug Store). Plea of guilty. Fine, \$300. (F. D. C. No. 29128. Sample Nos. 13820-K, 48547-K, 48655-K.)

Information Filed: June 29, 1950, Eastern District of Pennsylvania, against Jacob Sheckter, trading as Sheckter's Drug Store, Philadelphia, Pa.

INTERSTATE SHIPMENT: Between the approximate dates of May 31 and September 28, 1949, from the State of Maryland into the State of Pennsylvania.

ALLEGED VIOLATION: On or about October 24 and 28 and November 3, 1949, while the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and Section 502 (e) (1), the label of the repackaged tablets failed to bear the common or usual name of the drug, namely, sulfathiazole.

Further misbranding, Section 502 (f) (1), the repackaged *sulfathiazole tablets* failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Disposition: October 2, 1950. A plea of guilty having been entered, the court imposed a fine of \$300.

- 3244. Misbranding of Seconal Sodium capsules. U. S. v. Minter A. Dunn (Glade Spring Pharmacy). Plea of guilty. Defendant fined \$1,000 and placed on probation for one year. (F. D. C. No. 29115. Sample Nos. 2339-K to 2343-K, incl., 2345-K.)
- Information Filed: June 7, 1950, Western District of Virginia, against Minter A. Dunn, trading as the Glade Spring Pharmacy, Glade Spring, Va.
- INTERSTATE SHIPMENT: Between the approximate dates of May 3 and July 6, 1949, from the State of Indiana into the State of Virginia, of a quantity of Seconal Sodium capsules.
- ALLEGED VIOLATION: On or about August 6, 9, 12, 18, 20, and 22, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of *Seconal Sodium capsules* to be repacked and sold without a prescription, which acts of the defendant resulted in the capsules being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (1), the repackaged Second Sodium capsules, with the exception of those involved in one sale, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and when repackaged, the label failed to bear the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear directions for use.

- Disposition: October 2, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,000 and placed the defendant on probation for one year.
- 3245. Misbranding of Seconal Sodium capsules. U. S. v. Johnson's Drug Store, Inc., and George W. Johnson. Plea of guilty. Fine, \$50. (F. D. C. No. 29424. Sample Nos. 3025-K, 3026-K.)
- INFORMATION FILED: August 4, 1950, Eastern District of Virginia, against Johnson's Drug Store, Inc., and George W. Johnson, president of the corporation, Richmond, Va.
- INTERSTATE SHIPMENT: Between the approximate dates of January 18 and September 27, 1949, from the State of Indiana into the State of Virginia, of quantities of Seconal Sodium capsules.
- ALLEGED VIOLATION: On or about October 6 and 12, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused a number of the Seconal Sodium capsules to be repacked into bottles and to be sold without a prescription, which acts of the defendants resulted in the capsules being misbranded.
- NATURE of CHARGE: Misbranding, Section 502 (b) (1), the label of the repackaged Seconal Sodium capsules bore no statements containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), the repackaged capsules bore no label containing a statement of the quantity of the contents.

Further misbranding Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative the Federal Security Administrator,

after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

- DISPOSITION: September 13, 1950. A plea of guilty having been entered, the court imposed a fine of \$50.
- 3246. Misbranding of Seconal Sodium capsules. U. S. v. James Street Pharmacy, Inc. Plea of guilty. Fine of \$500, plus costs. (F. D. C. No. 26700. Sample Nos. 37388-K, 37391-K.)
- Information Filed: July 8, 1949, Western District of Washington, against James Street Pharmacy, Inc., Seattle, Wash.
- INTERSTATE SHIPMENT: Between the approximate dates of March 3 and September 10, 1948, from the State of Indiana into the State of Washington, of a quantity of Seconal Sodium capsules.
- ALLEGED VIOLATION: On or about November 27 and December 8, 1948, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of the Seconal Sodium capsules to be repacked and sold without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.
- NATURE of CHARGE: Misbranding, Section 502 (b) (2), the repackaged Seconal Sodium capsules bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (1), the label of the repackaged capsules failed to bear the common or usual name of the drug, namely, Seconal.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the directions "One at night if unable to sleep," borne on the labeling of the repackaged capsules, were not adequate directions for use.

- Disposition: September 25, 1950. A plea of guilty having been entered, the court imposed a fine of \$500, plus costs.
- 3247. Misbranding of Dexedrine Sulfate tablets. U. S. v. Glen P. James (James Drug). Plea of guilty. Fine, \$50. (F. D. C. No. 29470. Sample No. 64297-K.)
- Information Filed: October 18, 1950, District of South Dakota, against Glen P. James, trading as James Drug, Wagner, S. Dak.
- INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of South Dakota, of a quantity of *Dexedrine Sulfate tablets*.
- ALLEGED VIOLATION: On or about November 12, 1949, while the *Dexedrine Sulfate tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use.

DISPOSITION: October 24, 1950. A plea of guilty having been entered, the court imposed a fine of \$50.

3248. Misbranding of mammary extract. U. S. v. 22,000 Ampuls, etc. (F. D. C. No. 28719. Sample No. 73417-K.)

LIBEL FILED: February 28, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about December 29, 1949, by Specific Pharmaceuticals, Inc., from Bayonne, N. J.

PRODUCT: 22,000 1.1-cc. ampuls and 2,675 1.5-cc. ampuls of mammary extract at New York, N. Y.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article bore no label containing the name and place of business of the manufacturer, packer or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: August 3, 1950. The sole intervener having withdrawn his claim, judgment of condemnation was entered and the court ordered that the product be destroyed.

3249. Misbranding of Beatsol Rectifiers. U. S. v. 20 Packages * * *. (F. D. C. No. 29396. Sample No. 73363-K.)

LIBEL FILED: July 13, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about May 22, 1950, by G. & W. Laboratories, from Jersey City, N. J.

PRODUCT: 20 24-tablet packages of Beatsol Rectifiers at New York, N. Y.

LABEL, IN PART: (Package) "Contains 24 Tablets Beatsol Rectifiers For Both Sexes Formula Phosphorus—Ext. Nux Vomica ¼ gr. (Strychnine 55 gr.)—Ext. Damiana."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they suggested and implied that the article was an effective treatment for lost vitality, impotency, exhaustion, nervousness, and weakness in both sexes, whereas the article was not an effective treatment for such conditions; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings as are necessary for the protection of users since its labeling failed to warn that because of the strychnine ingredient more than the recommended dosage should not be taken and its use by elderly persons may be dangerous.

DISPOSITION: August 2, 1950. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3250. Adulteration of gentian root. U. S. v. 76 Bags * * * (F. D. C. No. 29707. Sample No. 73029-K.)

LIBEL FILED: August 29, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about March 2, 1950, from Trieste, Italy.

PRODUCT: 76 bags, each containing 122 pounds, of gentian root at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 20, 1950. William E. Martin Co., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for the purpose of fumigating, sifting, cleaning, and otherwise treating the product so as to bring it into compliance with the law, under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3251. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 3
Vials * * *. (F. D. C. No. 29398. Sample No. 1788-K.)

LIBEL FILED: On or about July 18, 1950, Northern District of Georgia.

ALLEGED SHIPMENT: On or about March 31, 1950, from Los Angeles, Calif.

PRODUCT: 3 10-cc. vials of chorionic gonadotropin at Atlanta, Ga.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article different from that which it purported to possess.

Misbranding, Section 502 (a), the label statement "One vial contains 5,000 I. U. of Chorionic Gonadotropin in a dried sterile powder which, when diluted with the accompanying 10 cc of diluent provides a solution having a potency of 500 I. U. per cc" was false and misleading as applied to an article which contained substantially less than 5,000 International Units of chorionic gonadotropin per vial.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1950. Default decree of condemnation and destruction.

3252. Adulteration of papaverine hydrochloride. U. S. v. 2 Bottles * * *. (F. D. C. No. 29399. Sample No. 81209-K.)

LIBEL FILED: July 14, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 11, 1949, from Los Angeles, Calif. PRODUCT: 2 bottles, each containing 16 ounces, of papaverine hydrochloride at Philadelphia, Pa.

Examination showed that the product was a cream-colored powder which did not meet all of the United States Pharmacopoeia tests for identity and the United States Pharmacopoeia requirement for the limit of organic impurities.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as, "Papaverine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard. The article was adulterated while held for sale after shipment in interstate commerce.

Disposition: September 21, 1950. Default decree of condemnation and destruction.

3253. Adulteration and misbranding of sulfamerazine tablets. U. S. v. 2 Bottles * * * (F. D. C. No. 29515. Sample No. 76150-K.)

LIBEL FILED: August 4, 1950, Northern District of Iowa.

ALLEGED SHIPMENT: On or about May 15, 1950, by Hopkins & Hopkins Pharmaceutical Co., Inc., from Philadelphia, Pa.

PRODUCT: 2 bottles each containing 1,000 sulfamerazine tablets at Milford, Iowa.

LABEL, IN PART: "1000 Sulfamerazine Tablets 7.7 Gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as, "Sulfamerazine Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in such compendium since the article contained less than 95 percent of the labeled amount of sulfamerazine. Misbranding, Section 502 (a), the label statement "Sulfamerazine Tablets 7.7 Gr." was false and misleading since the article contained less than 7.7 grains of sulfamerazine per tablet.

DISPOSITION: September 6, 1950. Default decree of condemnation and destruction.

3254. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 6 Cartons, etc. (F. D. C. No. 29507. Sample Nos. 68537-K to 68539-K, incl.)

LIBEL FILED: July 28, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about April 4, 1950, by the Norton Products Co., from Los Angeles, Calif.

PRODUCT: 18 cartons, each containing 24 1-pint bottles, of isopropyl alcohol rubbing compound at Tacoma, Wash.

LABEL, IN PART: (Bottle) "Norco [or "Fairmont Scented" or "Excello"] Isopropyl Alcohol Rubbing Compound Isopropyl Alcohol 70%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as, "Isopropyl Alcohol Rubbing Compound," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 68 percent isopropyl alcohol.

Misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70%" was false and misleading.

DISPOSITION: September 5, 1950. Default decree of condemnation and destruction.

3255. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 17 Cases * * * (F. D. C. No. 29202. Sample No. 68530-K.)

LIBEL FILED: May 10, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about March 16, 1950, by the Norton Products Co., from Los Angeles, Calif.

PRODUCT: 17 cases, each containing 24 1-pint bottles, of isopropyl alcohol rubbing compound at Seattle, Wash.

LABEL, IN PART: "Fairmont Scented Isopropyl Alcohol Rubbing Compound Isopropyl Alcohol 70%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as "Isopropyl Alcohol Rubbing Compound," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 68 percent isopropyl alcohol.

Misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70%" was false and misleading.

DISPOSITION: September 11, 1950. Default decree of condemnation and destruction.

3256. Adulteration and misbranding of prophylactics. U. S. v. 44 Gross * * * (F. D. C. No. 29244. Sample No. 53619-K.)

LIBEL FILED: On or about June 12, 1950, Southern District of Texas.

ALLEGED SHIPMENT: On or about May 1, 1950, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

PRODUCT: 44 gross of prophylactics at Mercedes, Tex. Examination of samples showed that 2.6 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacock Reservoir Ends."

NATURE of CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "An Aid In Preventing Venereal Disease * * * Tested * * * For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: July 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3257. Misbranding of Elemin and G & J Formula No. 701. U. S. v. 4 Bottles, etc. (F. D. C. No. 29685. Sample Nos. 75737-K, 75738-K.)

LIBEL FILED: August 11, 1950, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about September 28, 1949, by the G & J Distributors, from Berkeley, Calif.

PRODUCT: 4 700-tablet bottles of *Elemin* and 4 350-tablet bottles and 1 100-tablet bottle of *G & J Formula No. 701* at Milton, Wis., together with quantities of accompanying printed matter. The printed matter consisted of booklets entitled "Facts You Should Know" and "Food For Health," a letter dated March 22, 1949, headed "To all Dealers and Distributors," and leaflets entitled "Minerals For Health," "Did You Know That," and "Mineral Chart."

I.ABEL, IN PART: (Bottles) "Elemin As A Source Of The Minerals Iron And Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a Sedimentary Mineral Deposit" and "G & J Formula No. 701 Vitamins Each 3 tablets will supply: Vitamin A (Fish Liver Oils) 5000 U. S. P. Units Vitamin D (Irradiated Ergosterol) 1000 U. S. P. Units Vitamin B₁ (Thiamin Hcl and Yeast) 3.0 Mg. Vitamin B₂ (Riboflavin) 2.0 Mg. Vitamin B₀ (Pyridoxine Hcl) 1.0 Mg. Vitamin C (Ascorbic Acid) 50.0 Mg. Vitamin E (Alpha Tocopherol) 3.0 Mg. Niacin 20.0 Mg. Calcium Pantothenate 5.0 Mg. Concentrated Beef Liver Extract 65.0 Mg."

^{*}See also Nos. 3249, 3251, 3253-3256.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter were false and misleading since the articles were not effective for the purposes stated and implied. The statements represented that the articles were effective to prevent and correct tuberculosis, rickets, acidosis, headaches, asthma, congestion, indigestion, kidney disorders, nervousness, skin diseases, underweight, constipation, infection, obesity, low vitality, impatience, neuritis, skin disease, anemia, many degrees of eye trouble, nervous diseases, paralysis, muscular diseases, loss of weight, underdeveloped bones and teeth in children, mental slowness, bad nerves, mental depression, stomach ulcer, bone deformities, bad teeth, fatigability, behavior disturbances, nonadaptability, chronic gastritis, hyperacidity, diabetes, overweight, arthritis, heart diseases, lumbago, gland trouble of all sorts, reduced resistance to other diseases, severe colds, rheumatic heart diseases, bad blood, biliousness, slow digestion, stomach gas, heart palpitation and many other troubles caused by an overworked liver, poor memory, mental fatigue, catarrh, hardening processes, iron insufficiency, old-age deposits, neurasthenia, piling up of impurities, failure of liver to handle its materials, pain, pyorrhea, autointoxication, excess fat, pimples, failure of sores to heal, liver disorders, restlessness, toxic conditions, undue accumulation of waste matter, bad eyesight, baldness, gray hair, bad complexion, rundown weakened condition, poor resistance, sterility, lameness, and poor joints.

DISPOSITION: September 26, 1950. Default decree of forfeiture and destruction.

3258. Misbranding of Blanche Dunlap's massage cream and Mor-Hair scalp treament. U. S. v. 44 Bottles, etc. (F. D. C. No. 29379. Sample Nos. 67731-K to 67733-K, incl.)

LIBEL FILED: July 5, 1950, District of Utah.

ALLEGED SHIPMENT: On or about March 15, 1950, by Blanche Dunlap, Inc., Brown Palace Hotel Beauty Sales, from Denver, Colo.

PRODUCT: 44 4-ounce bottles of Blanche Dunlap's massage cream, and 10 cartons, each containing 2 4-ounce bottles and 1 4-ounce jar, of Mor-Hair Scalp Treatment at Salt Lake City, Utah, together with a number of leaflets entitled "The Mor-Hair Scalp Treatment."

RESULTS OF INVESTIGATION: The leaflet was received by the consignee from Blanche Dunlap, Inc., about four years previous to the seizure of the scalp treatment.

Analyses showed that the *Blanche Dunlap's massage cream* consisted essentially of castor oil, glycerin, and isopropyl alcohol, and that the *Mor-Hair scalp treatment* consisted essentially of the following: ("Trick 1") kerosene and saponifiable oils, such as olive oil and castor oil; ("Trick 2") creosote, mineral oil, and saponifiable oils; and ("Trick 3") petrolatum, with a small proportion of saponifiable oil.

Label, IN Part: (Bottle) "Blanche Dunlap's Massage Cream"; (carton) "Mor-Hail Scalp Treatment"; (bottle) "Blanche Dunlap's Trick 1" [or "Trick 2"]; and (jar) "Blanche Dunlap's Trick 3."

NATURE OF CHARGE: Blanche Dunlap's massage cream. Misbranding, Section 502 (a), the label statements "Now something can be done to glamorize your figure. Ask about the guaranteed Breast Massage Treatment Let us help you to get the contour you desire" were false and misleading since the article

was not effective for the purposes stated and implied; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and failed to declare the amount of isopropyl alcohol contained therein. The article was misbranded in the above respects when introduced into, and while in, interstate commerce.

Mor-Hair scalp treatment. Misbranding, Section 502 (a), the statement on the carton label "The Mor-Hair Scalp Treatment Keys to luxuriant healthy hair" was false and misleading since the article was not effective for the purposes stated and implied. Further misbranding, Section 502 (a), certain statements in the above-mentioned leaflet accompanying the scalp treatment were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for baldness, dandruff, itchy scalp, and scalp disorders; and that it would maintain a healthful condition of the scalp and restore original color to dull and faded hair, whereas the article was not effective for the purposes stated and implied. The article was misbranded by reason of the statement on the carton label when introduced into, and while in, interstate commerce, and it was misbranded by the statements in the leaflet while held for sale after shipment in interstate commerce.

Disposition: August 25, 1950. Default decree of condemnation. The court ordered that the products be disposed of by the United States marshal; accordingly, they were destroyed.

3259. Misbranding of Niagara devices. U. S. v. 31 Devices, etc. (F. D. C. No. 29074. Sample Nos. 71473-K, 71481-K, 71494-K, 71495-K.)

LIBEL FILED: April 21, 1950, Southern District of California; amended libel filed April 26, 1950.

ALLEGED SHIPMENT: On or about March 3 and April 12 and 20, 1950, by the Niagara Mfg. & Distributing Corp., from Buffalo, N. Y.; and on or about April 12, 1950, by the Niagara Massage Units Co., from Houston, Tex.

PRODUCT: 31 Niagara Portable Model No. 2 devices and 11 Niagara Hand Unit No. 1 devices, together with accompanying printed matter at Hollywood, Calif., in possession of the Niagara Units Co. Examination showed that the devices consisted of a vibrating electric motor mounted either in a metal cylinder (hand unit) or in an upholstered box (portable unit).

Label, IN Part: "Niagara of Adamsville Pennsylvania Portable Model No. 2 [or "Hand Unit No. 1"]."

Nature of Charge: Misbranding, Section 502 (a), the following statements in an accompanying circular entitled "Feel Better Look Years Younger" and similar statements in an accompanying circular entitled "Niagara Massage Units For Home Use" were false and misleading since the devices were not effective for the purposes stated and implied: "Feel Better Look Years Younger right in your own home the easy Niagara Way Reduce * * * The Portable Unit * * * to help you relieve those aching feet and legs, sore muscles, stiff joints * * * lack of vitality. * * * The Hand Unit can be used to * * * smooth out wrinkles * * * The Hand Unit is an indispensable aid for relieving that tired aching soreness across the shoulders and the back of the neck." The devices were misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), certain statements in other printed matter accompanying the devices were false and misleading since the devices were not an adequate and effective treatment for the conditions stated and implied, and the use of the devices would not fulfill the other promises of benefit stated and implied. The accompanying printed matter consisted of a leaflet entitled "Suggested Method of Treatment with Niagara Therapeutic, Reducing and Hand Units"; a case history letter, a letter beginning "I will answer the questions," and another letter beginning "We are truly concerned about you"; a circular entitled "Reduce at Home The Easy Niagara Way"; and a sales manual. The false and misleading statements in the printed matter represented and suggested that the devices were an adequate and effective treatment for overweight, head colds, high and low blood pressure, numbness of arms, extreme fatigue, hives; stiff knees, arms, and hands; pain in knees, sore feet, extreme nervous fatigue, migraine headaches, nervous tension, pallor, fungus growth on nails, arthritis, neuritis, insomnia, sinusitis, varicose veins, hemorrhoids, numbness and cold feet, periodic cramps, arteriosclerosis, atonic and spastic constipation, chronic phlebitis, catarrhal deafness, bronchitis, rhinitis, asthma, sciatica, myositis, general run-down conditions, and poor circulation; and that use of the devices would firm sagging facial muscles, remove double chin and wrinkles, insure the user normal good health, reduce the female generative organs to their normal nonpregnant size and condition, bring about normal menstruation, and lower the insulin requirement in diabetes. The devices were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: September 29, 1950. The Niagara Mfg. & Distributing Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3260. Misbranding of Sal-Vet Concentrate and Sal-Vet Mineral Supplement. U. S. v. 5 Cases, etc. (F. D. C. No. 29369. Sample Nos. 54791-K, 54792-K)

Libel Filed: June 28, 1950, Southern District of Mississippi; amended libel filed July 12, 1950.

ALLEGED SHIPMENT: On or about March 3, 1950, by the Sal-Vet Mfg. Co., from Cleveland, Ohio.

PRODUCT: 5 cases, each containing 12 3-pound cartons, of a product designated as Sal-Vet Concentrate, and 3 90-pound drums of a product designated as Sal-Vet Mineral Supplement, at Canton, Miss., together with a number of accompanying leaflets entitled "How To Make Your Own Sal-Vet."

Examination disclosed that the product under both designations was of the same composition, and that it consisted essentially of limestone, approximately 67 percent; 'sulfur, 4.5 percent; 'Glauber's salt, 3.3 percent; iron sulfate, 2 percent; and charcoal; and that it contained no significant proportion of any animal feeding oil or linseed oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the accompanying leaflets were false and misleading since the articles were not effective for the purposes stated and implied: "Sal-Vet will keep your livestock in the best of condition; worm free, strong and sturdy with resistance

power against sickness * * * by using Concentrate to make your own worm destroyer and conditioner tonic."

Further misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the article contained no significant proportion, if any, of animal feeding oil or linseed oil: (Label) "Ingredients * * * Animal Feeding Oil" and (leaflet) "It consists of 100% Chemicals and Minerals, such as * * * Raw Linseed Oil."

DISPOSITION: September 21, 1950. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3241 TO 3260

PRODUCTS

PRODUCTS			
N. J. No.	N. J. No.		
Alcohol rubbing compound, iso-	Massage cream, Blanche Dun-		
propyl 3254, 3255	lap's 3258		
Beatsol Rectifiers (drug) 3249	Mor-Hair scalp treatment 3258		
Chorionic gonadotropin 3251	Niagara devices 3259		
Devices 3256, 3259	Papaverine hydrochloride 3252		
Dexedrine Sulfate tablets 3241, 3247	Prophylactics 3256		
Dunlap's, Blanche, massage	Sal-Vet Concentrate and Sal-Vet		
cream 3258	Mineral Supplement 3260		
G & J Formula No. 701 3257	Seconal Sodium capsules 3244-3246		
Gentian root 3250	Sulfamerazine tablets 3253		
Gonadotropin, chorionic 3251	Sulfathiazole lozenges 3241		
Hair and scalp preparations 3258	tablets 3242, 3243		
Isopropyl alcohol rubbing com-	Tuinal capsules 3241		
pound 3254, 3255	Veterinary preparations 3260		
Mammary extract 3248	Vitamin preparation 3257		
SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS			
N. J. No.	N. J. No.		

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS			
N.	J. No. 1	N	J. No.
Brown Palace Hotel Beauty		G & J Distributors:	
Sales:		Elemin and G & J Formula No.	
Blanche Dunlap's massage		701	3257
cream and Mor-Hair scalp		G. & W. Laboratories:	
treatment	3258	Beatsol Rectifiers (drug)	3249
Dean Rubber Mfg. Co.:		Glade Spring Pharmacy. See	
prophylactics	3256	Dunn, M. A.	
Doerr, E. A.:		Hopkins & Hopkins Pharmaceu-	
sulfathiazole lozenges, Dexe-		tical Co., Inc.:	
drine Sulfate tablets, and		sulfamerazine tablets	3253
Tuinal capsules	3241	James, G. P.:	
Doerr's Drug Store. See Doerr,		Dexedrine Sulfate tablets	3247
E. A.:		James Drug. See James, G. P.	
Dunlap, Blanche, Inc.:	1	James Street Pharmacy, Inc.:	
Blanche Dunlap's massage	4	Seconal Sodium capsules	3246
cream and Mor-Hair scalp		Johnson, G. W.:	
treatment	3258	Seconal Sodium capsules	3245
Dunn, M. A.:		Johnson's Drug Store, Inc.:	
Seconal Sodium capsules	3244	Seconal Sodium capsules	3245

N. J. No.	N. J. No
Morgan, A. R.:	Sal-Vet Mfg. Co.:
sulfathiazole lozenges, Dexe-	Sal-Vet Concentrate and Sal-
drine Sulfate tablets, and	Vet Mineral Supplement 3260
Tuinal capsules 3241	Sheckter, Jacob:
Niagara Mfg. & Distributing	sulfathiazole tablets 3245
Corp.:	Sheckter's Drug Store. See
Niagara devices 3259	Sheckter, Jacob.
Niagara Massage Units Co.:	Specific Pharmaceuticals, Inc.:
Niagara devices 3259	mammary extract 3248
Norton Products Co.:	Titus, S. S.:
isopropyl alcohol rubbing com-	sulfathiazole tablets 3242
pound 3254, 3255	Titus Pharmacy. See Titus, S. S.
-	•

DESCRIPTION OF THE PERSON OF T



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3261-3280

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs. Washington, D. C., February 12, 1951

CONTENTS*

Page	Page
Drug actionable because of poten-	Drugs actionable because of con-
tial danger when used accord-	tamination with filth 248
ing to directions 240	Drugs and devices actionable be-
Drug for veterinary use 240	cause of deviation from official
Drugs actionable because of fail-	or own standards 249
ure to bear adequate direc-	Drugs actionable because of false
tions or warning statements 240	and misleading claims 250

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3265, 3266; omission of, or unsatisfactory, ingredients statements, Nos. 3265, 3267, 3269; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3262-3266, 3269; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3262-3266, 3278; labeling information not likely to be understood by the ordinary individual under customary conditions of purchase and use, No. 3267; cosmetics, actionable under the drug provisions of the Act, No. 3280.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUG FOR VETERINARY USE

3261. Adulteration and misbranding of P-V-F-M. U. S. v. 69 Bottles * * *. (F. D. C. No. 29719. Sample No. 85305-K.)

LIBEL FILED: September 7, 1950, District of South Dakota.

ALLEGED SHIPMENT: During September or October 1949, by Dr. I. W. Martin, from Sibley, Iowa.

PRODUCT: 69 250-cc. bottles of *P-V-F-M* at Sioux Falls, S. Dak. Analysis showed that the product contained materially more sulfanilamide and materially less tyrothricin than declared upon the label. The article was strongly alkaline. It completely inactivated penicillin G almost immediately on contact.

Label, IN Part: "P-V-F-M A Vehicle for incorporating Penicillin G for treating Mastitis due to Streptococcus Agalactiae * * * Ingredients Sulfanilamide, 3 grs./fl. oz. Tyrothricin 4.7 mgms./fl. oz. Water * * * Manufactured by Nelson Laboratories, Sioux Falls, South Dakota."

NATURE of CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "A Vehicle for incorporating Penicillin G" was misleading since the article inactivated penicillin G almost immediately upon contact, and, further, the label statement "Manufactured By Nelson Laboratories, Sioux Falls, South Dakota" was false and misleading since the article was not manufactured by Nelson Laboratories, nor at Sioux Falls, S. Dak.; and, Section 502 (j), the article by reason of its alkalinity was dangerous to health when used as directed on the bottle label, namely, "* * inject the entire contents of this bottle into one infected quarter through the teat canal. It may be * * left in the quarter of dry cows."

DISPOSITION: October 17, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3262. Misbranding of Dexedrine Sulfate tablets. U. S. v. Mark Halsey Drug Stores, William C. Reynolds, Arthur D. Purswell, and James C. Richards.
Pleas of nolo contendere. Mark Halsey Drug Stores fined \$500; William C. Reynolds, Arthur D. Purswell, and James C. Richards each fined \$100.

(F. D. C. No. 29431. Sample Nos. 68012-K, 68015-K, 68016-K, 68095-K.)

Information Filed: July 15, 1950, Northern District of Texas, against Mark Halsey Drug Stores, a partnership, Lubbock, Tex., and William C. Reynolds, Arthur D. Purswell, and James C. Richards. The Mark Halsey Drug Stores was charged with causing the sales in each of the 4 counts of the information; William C. Reynolds was charged with the sale in count 1; Arthur D. Purswell was charged with the sale in counts 2 and 4; and James C. Richards was charged with the sale in count 3.

INTERSTATE SHIPMENT: On or about October 11, 1949, from Philadelphia, Pa., into the State of Texas, of quantities of Dexedrine Sulfate tablets.

- ALLEGED VIOLATION: On or about November 16, 18, 19, and 21, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants repacked and caused to be repacked a number of tablets of the drug, and sold and caused the tablets to be sold without a prescription, which acts of the defendants resulted in the drug being misbranded. Portions of the repackaged Dexedrine Sulfate tablets were labeled in part: "Mark Halsey Drug Store No. 2 College and Broadway Dial 4656 Lubbock, Texas."
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (b) (1), portions of the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the repackaged drug bore no labeling containing directions for use.
- Disposition: September 27, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$500 against the partnership on count 1 and suspended the imposition of sentence against the partnership on the remaining 3 counts; William C. Reynolds was fined \$100 on count 1; Arthur D. Purswell was fined \$100 on count 2, was given a suspended sentence, and was placed on probation for 1 year on count 4; and James C. Richards was fined \$100 on count 3.
- 3263 Misbranding of diethylstilbestrol tablets, Dexedrine Sulfate tablets, and sulfadiazine and sodium bicarbonate tablets. U. S. v. Evans Drug Co., Inc., and Robert H. Wyatt, Walter M. Boyett, and Ralph H. Duncan. Pleas of nolo contendere by all defendants. The corporation, Robert H. Wyatt, and Walter M. Boyett each fined \$100; Ralph H. Duncan fined \$50. (F. D. C. No. 29127, Sample Nos. 27074-K, 61723-K, 61725-K, 61741-K, 62073-K.)
- Information Filed: June 7, 1950, Western District of Kentucky, against Evans Drug Co., Inc., Mayfield, Ky., and Robert H. Wyatt, president, and Walter M. Boyett and Ralph H. Duncan, pharmacists.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Kentucky, of quantities of diethylstilbestrol tablets, Dexedrine Sulfate tablets, and sulfadiazine and sodium bicarbonate tablets.
- ALLEGED VIOLATION: On or about September 10, 24, and 28, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.
 - The five counts of the information charged violations by the corporation and its president, Robert H. Wyatt. Ralph H. Duncan was joined as a defendant in count 1, charged with making the sale involved in that count, and Walter M. Boyett was joined as a defendant in counts 4 and 5, charged with making the sales involved in those counts.
- Nature of Charge: Misbranding, Section 502 (b) (1), the repackaged diethylstilbestrol tablets and the Dexedrine Sulfate tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), they failed to bear labeling containing directions for use; and, Section

- 502 (f) (2), the *sulfadiazine and sodium bicarbonate tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- DISPOSITION: October 23, 1950. Pleas of nolo contendere having been entered on behalf of the corporation and Robert H. Wyatt, the court fined each of these defendants \$100 and dismissed counts 3, 4, and 5 against them. Pleas of nolo contendere having been entered by Walter M. Boyett to counts 4 and 5 and by Ralph H. Duncan to count 1, the former was fined \$100 and the latter \$50.
- 3264. Misbranding of Dexedrine Sulfate tablets, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets. U. S. v. Walter W. Evans and Robert A. Binford (Evans Drug Co.). Pleas of nolo contendere. Each defendant fined \$150. (F. D. C. No. 29124. Sample Nos. 61643-K, 61664-K, 61678-K to 61680-K, incl., 61753-K.)
- INFORMATION FILED: June 7, 1950, Western District of Kentucky, against Walter W. Evans and Robert A. Binford, trading as the Evans Drug Co., a partnership, Fulton, Ky.
- INTERSTATE SHIPMENT: From the States of Pennsylvania, Missouri, and Indiana, into the State of Kentucky, of quantities of Dexedrine Sulfate tablets, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets.
- ALLEGED VIOLATION: On or about September 13, 18, and 24, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of *Dexedrine Sulfate tablets*, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: October 23, 1950. Walter W. Evans and Robert I. Binford having entered pleas of nolo contendere, the court fined the former \$150 on counts 1, 2, and 3, and the latter \$150 on counts 4, 5, and 6. Counts 4, 5, and 6 against Walter W. Evans and counts 1, 2, and 3 against Robert I. Binford were dismissed.
- 3265. Misbranding of Triple Sulfonamides tablets, Dexedrine Sulfate tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules. U. S. v. Carl E. Neels. Plea of guilty. Fine, \$1,100. (F. D. C. No. 29485. Sample Nos. 60867-K, 60868-K, 60938-K, 60939-K, 60954-K, 60955-K, 60974-K.)
- Information Filed: July 25, 1950, Eastern District of Missouri, against Carl E. Neels, a pharmacist for Neels Drugs, St. Louis, Mo.
- INTERSTATE SHIPMENT: From the States of Ohio, Pennsylvania, Indiana, and New York, into the State of Missouri, of quantities of Triple Sulfonamides

tablets, Dexedrine Sulfate tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules.

ALLEGED VIOLATION: On or about August 4, 20, 22, and 25, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of such drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs, with the exception of the *diethylstilbestrol tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *pentobarbital sodium capsules* failed to bear the name and quantity of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the *Triple Sulfonamides tablets* were fabricated from two or more ingredients, and when repackaged, their label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *Triple Sulfonamides tablets* and *diethylstilbestrol tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Disposition: August 18, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,100.

3266. Misbranding of Desoxyn Hydrochloride tablets, Combisul tablets, and Seconal Sodium capsules. U. S. v. William Chester Dickson (Medical Arts Pharmacy), and Oliver A. Roholt, Sr. Pleas of guilty. William Chester Dickson fined \$150 and Oliver A. Roholt, Sr., fined \$25. (F. D. C. No. 28154. Sample Nos. 41071-K, 41072-K, 50629-K to 50632-K, incl.)

Information Filed: September 15, 1950, District of Montana, against William Chester Dickson, trading as the Medical Arts Pharmacy, Great Falls, Mont., and Oliver A. Roholt, Sr., a pharmacist.

INTERSTATE SHIPMENT: From the States of Indiana, Washington, and New Jersey, into the State of Montana, of quantities of Desoxyn Hydrochloride tablets, Combisul tablets, and Seconal Sodium capsules.

ALLEGED VIOLATION: On or about May 25 and 26, 1949, while the drugs were being held for sale after shipment in interstate commerce, William Chester Dickson caused various quantities of the drugs to be repacked and sold without a prescription, and on May 25, 1949, William Chester Dickson and Oliver A. Roholt, Sr., caused an additional quantity of Combisul tablets to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged tablets and capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged Combisul tablets and a portion of the repackaged Desoxyn Hydrochloride tablets failed

to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs bore no labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the drug failed to bear a label containing the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), all of the repackaged drugs failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the repackaged Desoxyn Hydrochloride tablets and Combisul tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 15, 1950. Pleas of guilty having been entered, the court fined William Chester Dickson \$150 and Oliver A. Roholt, Sr., \$25.

3267. Misbranding of Special tablets. U. S. v. 2 Bottles * * *. (F. D. C. No. 29726. Sample No. 81219-K.)

LIBEL FILED: September 11, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 26 and April 1, 1950, by D. M. Olmstead Laboratories, from Camden, N. J.

PRODUCT: 2 bottles of Special tablets at Darby, Pa.

LABEL, IN PART: (Bottles) "3500 C. T. Special (Dr. Herting) Orchic Substance—1 gr. Prostate Substance—1 gr. d1-Desoxyephedrine Hydrochloride 1/10 gr. Yohimbine Hydrochloride 1/10 gr. Oil Peppermint q.s."

Nature of Charge: Misbranding, Section 502 (c), the information required by, and under authority of, Section 502 (e) (2) to appear on the label, namely, the common or usual names of each active ingredient, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the names of the inert ingredients were arranged in such manner on the label as not to inform the purchaser which of the ingredients were inactive; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it bore no directions for use.

DISPOSITION: October 17, 1950. Default decree of condemnation and destruction.

3268. Misbranding of Elixir Aletris-Helonias Compound. U. S. v. 4 Bottles, etc. (F. D. C. No. 29245. Sample No. 60095–K.)

LIBEL FILED: May 29, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 2, 1950, by Parke, Davis & Co., Detroit, Mich.

PRODUCT: 4 1-pint bottles and 2 1-gallon bottles of Elixir Aletris-Helonias Compound at Chicago, Ill.

Label, In Part: "Elixir Aletris-Helonias Compound Each Fluid Ounce Represents Aletris (Star Grass)—30 Grains Helonias (False Unicorn)—30 Grains Caulophyllum (Blue Cohosh)—30 Grains Mitchella (Squaw Vine)—

30 Grains Viburnum Opulus (Cramp Bark)—15 Grains Alcohol 27 Percent Adult Dose—1 To 2 Fluid Drachms (4 to 8 cc.) As Directed By The Physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions found in the labeling, namely, "1 To 2 Fluid Drachms (4 to 8 cc.) As Directed By The Physician," failed to reveal the condition or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: September 12, 1950. Default decree of condemnation and destruction.

3269. Misbranding of Hollis cold and grippe remedy, Hollis Indian herbs, and Hollis tonic for men. U. S. v. 28 Bottles, etc. (F. D. C. No. 29665. Sample Nos. 62334-K, 62336-K, 62337-K.)

LIBEL FILED: July 28, 1950, District of Massachusetts.

ALLEGED SHIPMENT: On or about March 22 and October 6 and 25, 1949, from New York, N. Y., Jersey City, N. J., and Detroit, Mich.

PRODUCT: 28 100-tablet bottles and 27 300-tablet bottles of Hollis cold and grippe remedy, 65 3-ounce packages of Hollis Indian herbs, and 65 50-tablet bottles and 43 250-tablet bottles of Hollis tonic for men at Boston, Mass., in possession of the consignee, Thomas Hollis Co. The products had been shipped in bulk and subsequently were repacked and labeled by the consignee.

Examination showed that the *Hollis cold and grippe remedy* was a mixture of lactose and small amounts of plant extractives, including atropine; that the *Hollis Indian herbs* was a mixture of cut herbs, including prickly ash bark, dandelion root, gentian root, yellow dock root, sarsaparilla root, Chimaphila, boldo leaves, and cascara bark; and that the *Hollis tonic for men* contained zinc phosphide and nux vomica alkaloids, including strychnine.

LABEL, IN PART: "Hollis A. B. B. Vegetable Cold and Grippe Remedy," "Hollis Indian Herbs A Vegetable Remedy," and "Hollis Tonic For Men."

NATURE OF CHARGE: Hollis cold and grippe remedy. Misbranding, Section 502 (a), the label statement "Cold and Grippe Remedy" was false and misleading since the article was not an effective treatment for colds and grippe; Section 502 (b) (2), the article failed to bear a label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of the atropine contained therein.

Hollis Indian herbs. Misbranding, Section 502 (a), the label statements "A Vegetable Remedy Blood Tonic Spring Medicine * * * An All Year Round Medicine" were false and misleading since such statements represented and suggested that the article was effective in the treatment of many unspecified diseases of the human body and had a specific remedial effect on the blood, whereas the article was not effective in the treatment of such diseases and did not have a specific remedial effect on the blood; and, Section 502 (f) (2), the article was essentially a laxative, and its labeling failed to warn that the article should not be used in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that continued use may result in dependence upon laxatives.

Hollis tonic for men. Misbranding, Section 502 (a), the label statement "Tonic For Men Vim and Vigor" was false and misleading since such statement represented and suggested that the article was effective in increasing the

strength and vigor of males, whereas the article was not effective for such purposes; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the name, and quantity or proportion of strychnine contained therein; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage in such manner and form as are necessary for the protection of users since the article contained strychnine, and its label failed to warn that more than the recommended dosage should not be taken and that its use by elderly persons may be dangerous.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITON: October 9, 1950. Default decree of condemnation and destruction.

3270. Misbranding of Citru-Mix. U. S. v. 152 Bottles, etc. (F. D. C. No. 28320. Sample No. 52932-K.)

Libel Filed: December 2, 1949, Western District of Kentucky; amended libel filed April 25, 1950.

ALLEGED SHIPMENT: On or about October 18, 1949, by the Nu-Way Corp., from Grand Rapids, Mich.

Product: 152 bottles, each containing 80 tablets, of *Citru-Mix*, and 30 4-ounce bottles and 32 2-ounce bottles of a powder of *Citru-Mix* at Bowling Green, Ky., together with a number of display cards entitled "Citru-Mix."

Examination showed that the tablets consisted essentially of sodium salicylate, aspirin, calcium succinate, citric acid, sodium citrate, and vitamin B_1 ; and that the powder consisted essentially of sodium salicylate, citric acid, sodium citrate, vitamin B_1 , and sugar.

Nature of Charge: Misbranding, Section 502 (a), the labeling of the articles represented and suggested that the articles were effective in the treatment and cure of rheumatism, arthritis, and neuritis, which was false and misleading since the articles were not effective in the treatment and cure of such conditions; and the statements on the bottle labels of the powder and tablets "active ingredients * * * citric acid, sodium citrate, dextrose" and (tablets only) "calcium succinate" were false and misleading since the ingredients of the articles, citric acid, sodium citrate, and dextrose, and (tablets only) calcium succinate, were not active in the treatment of the conditions for which the articles were intended.

Further misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the labeling failed to bear adequate directions for use in the treatment and cure of rheumatism, arthritis, neuritis, lumbago, sciatica, gout, and the other conditions for which the articles were intended.

DISPOSITION: November 13, 1950. The Nu-Way Corp., claimant, having filed an answer but having failed to appear at the time the case was called for hearing, judgment of condemnation was entered and the court ordered that the products be destroyed.

3271. Misbranding of Missouri Brand Iren Quota tablets, Missouri Brand Golden Seal Plus Fennel tablets, and Missouri Brand Live Spot vitamin E capsules. U. S. v. 794 Bottles, etc. (F. D. C. No. 28248. Sample Nos. 27509-K, 27510-K, 27520-K, 61595-K to 61597-K, incl.)

LIBEL FILED: October 31, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: During the year 1946, from Chicago, Ill., and on or about March 25, 1948, from Detroit, Mich.

PRODUCT: 794 35-tablet bottles of Missouri Brand Iron Quota tablets, 372 65-tablet bottles of Missouri Brand Golden Seal Plus Fennel tablets, and 194 100-capsule bottles of Missouri Brand Live Spot vitamin E capsules at St. Louis, Mo.

RESULTS OF INVESTIGATION: The products were offered by Lelord Kordel at a series of lectures given by him at St. Louis, Mo., between September 26 and October 5, 1949, and by leaflets distributed at the same time and place, for the following purposes:

Missouri Brand Iron Quota tablets. To keep blood in a normal condition, vital and alive; to help build up the red coloring matter of blood; to enable the blood to extract the full amount of iron from one's food; to effect an amazing change in the consumer within three months' time by helping to build up the iron substance in his blood, enabling him to draw a lot more iron from his food, and building his blood to such a condition that on a right diet, it will take care of itself; to make the blood rich and strong; to remedy blood-iron deficiency; to recharge, rebuild, and revitalize the blood in 90 days; to be of value to exhausted glands; and to correct conditions resulting from bad nutrition, poor quality of blood, and insufficient minerals;

Missouri Brand Golden Seal Plus Fennel tablets. To keep the body clean of mucus; to soothe; to help keep the cells of the body clean; to remedy digestive disorders and debilitated conditions of the mucous membrane; to treat various gastric complaints; to be of advantage to most dyspeptics; to treat catarrhal, a condition, which is stagnant mucus that wants to force its way out; to be of value in a catarrhal condition of the urinary tract; to act as a powerful cleanser of stale, thick mucous deposits in the body; to help the functioning of liver and kidneys; to be of use to people troubled with getting up nights and whose passage of urine is very scanty; to relieve congestion; to influence the contamination of the impurities of the body that clog it; to accomplish almost wonders in that respect within two months; to be of great value to women undergoing the change of life; to help increase the tone of the uterus, which is important during the menopause; to curb indigestion of dyspeptics; to cleanse the body of impurities; to get the digestive machinery going; to effect a detectable change within two weeks; to effect the passing out of mucus through the nose, the coughing up of old, stale mucus, and its elimination through the urine and the bowels; to cause one to feel much better and to obtain more energy and nourishment from food by absorbing more out of it; to eliminate gas and to get all of the mucus out of the body; to keep the digestive machinery always in perfect functioning order and to bestow wonderful benefits as far as the entire digestive machine is concerned; to get rid of all that thick, stagnant mucus that may have accumulated; to stop snoring; to work as a cleanser of putrefactive materials; to tone up the glands of the body; to keep the lymph system in good condition, so that the lymph will filter and hold invading organisms until they can be destroyed by the leucocytes; to stimulate the liver and pancreas; to keep the pores clean and free of foreign deposits, such as slime and mucus; to give the glands the benefit of the radioactive substances which are in the goldenseal herb; to have a beneficial effect on all of the glands of the body; and to furnish the glands with vital elements, which the goldenseal herb contains, and which we call radioactive elements, that help to stimulate

the glands of the body to a more normal activity, and to be of important value in catarrhal conditions, particularly of the genito-urinary tract;

Missouri Brand Live Spot vitamin E capsules. To help prevent miscarriage; to correct a very rapid and fluttering heart; to stop cramps in the legs; to prevent muscles drying up; to help correct loss of elasticity of the muscles; and to cure stiffness of the arm; for heart disease and for helping the heart; to exert an extremely important effect on the entire reproductive system of the human; to prevent male sterility; to prevent and correct female sterility; for women going through the menopause; to exert on the glandular system of the body; to act as a substitute for digitalis; to supply a need of the body, heart, brain, reproductive organs, and personality glands; and for low blood pressure.

I.ABEL, IN PART: (Bottle) "Missouri Brand Iron Quota * * * Contains Ferric Citrate as a source of iron," "Missouri Brand Golden Seal Plus Fennel Tablets," and "Missouri Brand Live Spot Vitamin E."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 23, 1950. Joseph Stoller, St. Louis, Mo., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. Repacking and relabeling operations were completed on or about June 15, 1950.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3272. Adulteration of cocillana bark. U. S. v. 172 Bags * * * (F. D. C. No. 29098. Sample No. 73014-K.)

LIBEL FILED: May 5, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about August 15, 1947, from Guapi, Colombia.

PRODUCT: 172 100-pound bags of cocillana bark at Staten Island, N. Y.

Nature of Charge: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, and of a decomposed substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: October 24, 1950. Default decree of condemnation and destruction.

3273. Adulteration of orrisroot, juniper berries, and yellow dock root. U. S. v. 133 Bags, etc. (F. D. C. No. 29060. Sample Nos. 73008-K, 73010-K, 73011-K.)

LIBEL FILED: April 13, 1950, District of New Jersey.

ALLEGED SHIPMENT: On or about April 1, 1946, and during February 1948, from Livorno, Italy; and on a date unknown, from Boone, N. C.

PRODUCT: 133 154-pound bags of orrisroot, 61 120-pound bags of juniper berries, and 1 300-pound bale of yellow dock root at Hoboken, N. J.

NATURE of CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of dead and live insects and insect excreta.

Further adulteration, Section 501 (b), the *orrisroot* and *juniper berries* purported to be, and were represented as, drugs, the names of which are recognized in the National Formulary, an official compendium, and the *yellow dock root* purported to be, and was represented as, a drug, the name of which is recognized in the Homeopathic Pharmacopoeia of the United States, an official compendium; and the purity and quality of the articles fell below the standards set forth in the respective compendia for such drugs. The compendia provide that vegetable drugs are to be as free as practicable from insects, or other animal life and animal excreta, whereas the articles were contaminated with dead and live insects and insect excreta.

The articles were adulterated while held for sale after shipment in interstate commerce.

Disposition: July 24, 1950. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the products be released under bond for the purpose of segregating and destroying those articles determined to be incapable of successful salvage, and for the purpose of treating the remaining articles by fumigating, cutting, or blowing, or by similar salvage procedure, so as to eliminate and destroy the objectionable portions of the articles, under the supervision of the Federal Security Agency.

All of the *yellow dock root* was found to be unfit and was destroyed. The *orrisroot* and *juniper berries* were cleaned and sorted, with the result that approximately 2,787 pounds of the *orrisroot* and 871 pounds of the *juniper berries* were classified as unfit. The good portions, 21,952 pounds of *orrisroot* and 3,769 pounds of *juniper berries*, then were released for disposition by the claimant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3274. Adulteration of Areca nuts. U. S. v. 30 Bags * * * *. (F. D. C. No. 29511. Sample No. 77534-K.)

LIBEL FILED: On or about August 4, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 11, 1950, by the William E. Martin Co., from Peoria, Ill.

PRODUCT: 30 bags, each containing from 100 to 194 pounds, of Areca nuts at St. Louis, Mo.

Nature of Charge: Adulteration, Section 501 (b), the article purported to be "Areca nuts," a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since the article contained insect-damaged and moldy nuts and insects and insect parts. (The National Formulary provides that vegetable drugs are to be as free as practicable from molds, insects, and other animal life, and that they shall show no evidence of deterioration.)

Disposition: August 28, 1950. Default decree of condemnation and destruction.

^{*}See also Nos. 3261, 3273.

3275. Adulteration of citrate of magnesia. U. S. v. 30 Cases * * * (F. D. C. No. 29528. Sample No. 35505–K.)

LIBEL FILED: August 16, 1950, District of Nevada.

ALLEGED SHIPMENT: On or about July 19, 1950, by the Robinson Laboratories, from San Francisco, Calif.

PRODUCT: 30 cases, each containing 24 12-ounce bottles, of citrate of magnesia at Reno, Nev.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as, "Solution of Magnesium Citrate," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard. (The product contained less magnesium citrate than required by the Pharmacopoeia.)

DISPOSITION: September 15, 1950. Default decree of condemnation and destruction.

3276. Adulteration and misbranding of prophylactics. U. S. v. 2,592 Boxes

* * * (F. D. C. No. 29892. Sample No. 89844-K.)

LIBEL FILED: September 22, 1950, District of Nebraska.

ALLEGED SHIPMENT: On or about September 2, 1950, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

PRODUCT: 2,592 boxes of *prophylactics* at Omaha, Nebr. Examination of samples showed that 3.7 percent were defective in that they contained holes.

LABEL, IN PART: "12 Deans Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "An Aid in Preventing Venereal Disease * * * For Your Protection" were false and misleading as applied to an article containing holes.

Disposition: October 19, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3277. Misbranding of Veronica mineral water. U. S. v. Veronica Sales Co., Ltd., and Frank W. Cole. Plea of nolo contendere. Each defendant fixed \$20. (F. D. C. No. 25620. Sample Nos. 26698-K, 29439-K.)

Information Filed: April 19, 1950, Western District of Tennessee, against Veronica Sales Co., Ltd., a partnership, Santa Barbara, Calif., and Frank W. Cole, a partner.

ALLEGED SHIPMENT: On or about February 4 and March 29, 1948, from the State of Tennessee into the States of Missouri and Texas.

Product: Analysis disclosed that the product was a mineral water containing magnesium sulfate (epsom salt) as the principal ingredient.

LABEL, IN PART: (Bottle) "Veronica California Natural Springs Water." Circulars entitled "Arthritis Routed By Ancient California Mineral Water" and "Veronica Water" accompanied the shipment of February 4, 1948, and a circular entitled "Veronica Health Water Is Back" accompanied the shipment of March 29, 1948.

^{*}See also Nos. 3269, 3270, 3276; veterinary preparation, No. 3261.

Nature of Charge: Misbranding, Section 502 (a), certain statements in the labeling of the shipment of February 4, 1948, represented and suggested that the product would be efficacious in the cure, mitigation, and treatment of arthritis, rheumatism, high blood pressure, and acidity; disorders of the stomach, intestines, kidneys, liver, and gall bladder; gallstones, stomach ulcers, athlete's foot, burns, cuts, sprains, inflammation, poison oak, and skin disorders; and that it would be efficacious to promote health; and in addition, certain statements in the labeling of the shipment of March 29, 1948, represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of dyspepsia, dropsy, urinary and bladder troubles, gallstones, impaired functions of the kidneys and liver, renal calculi, chronic constipation, fermentative indigestion, jaundice, spastic colon, arthritis, stomach ulcers, excess acidity, high blood pressure, and stone and gravel in the bladder; that it would be efficacious to stimulate the liver; that it would be efficacious as an anthelmintic and as a gastric and intestinal tonic; that it would be efficacious to restore the bowels to normal and supply much useful material for the nutrition of important tissues; and that it would be efficacious to promote health. These representations in the labeling were false and misleading since the product would not be efficacious for the purposes claimed.

DISPOSITION: November 13, 1950. The case having been transferred from the Western District of Tennessee to the Southern District of California, pleas of nolo contendere were entered and the court imposed a fine of \$20 against each defendant.

3278. Misbranding of Hett's Serum. U. S. v. 1 Vial, etc. (F. D. C. No. 29720. Sample No. 32376-K.)

LIBEL FILED: September 12, 1950, Northern District of California.

ALLEGED SHIPMENT: During the month of July, 1950, by Dr. M. O. Moore, from Windsor, Canada.

PRODUCT: 1 vial containing 10 cc. of *Hett's Serum* at Los Gatos, Calif., together with a number of booklets entitled "The Hett Cancer Treatment and Research Foundation."

Examination of the product indicated that it was a dilute solution of nitrogenous material from animal tissue.

RESULTS OF INVESTIGATION: A copy of the booklet was originally obtained by Dr. M. O. Moore from an individual in Los Angeles, Calif. Dr. Moore had the booklet reprinted and kept the booklet on hand to give to his patients.

LABEL, IN PART: "Hett's Serum."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying booklet were false and misleading since they represented and suggested that the article was effective in the treatment of cancer, whereas the article was not effective for such purpose; and, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1950. Default decree of condemnation and destruction.

3279. Misbranding of Rutang Botanical Laxative Compound, Rutang Super White Liniment, and Rutang tablets. U. S. v. 41 Bottles, etc. (F. D. C. No. 29389. Sample Nos. 81860–K to 81862–K, incl.)

LIBEL FILED: July 21, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about May 16 and 26 and June 5, 1950, from Columbus, Ohio.

PRODUCT: 41 1-pint bottles of Rutang Botanical Laxative Compound, 71 1-pint bottles of Rutang Super White Liniment, and 36 100-tablet bottles of Rutang tablets at Miami, Fla., in possession of the Vita Health Co., together with a number of circulars entitled "Rutang Price List No. 11."

Analysis showed that the *Rutang Botanical Laxative Compound* was an aqueous solution of plant extractives, including emodin; that the *Rutang Super White Liniment* was an aqueous ammoniacal suspension of turpentine and camphor; and that the *Rutang tablets* contained aspirin and calcium succinate.

RESULTS OF INVESTIGATION: The circulars described above were printed locally and were given to customers of the consignee.

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circular were false and misleading. The statements represented and suggested that the Rutang Botanical Laxative Compound was effective in the treatment of gastritis; that it was effective for providing strength and vitality, for making one feel better, for relieving pains, for curing the human body, and for preventing suffering; and that the Rutang Super White Liniment and the Rutang tablets were effective in the treatment of rheumatism, neuritis, and arthritis. The articles were not effective treatments for the conditions stated and implied.

The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 12, 1950. Default decree of forfeiture and destruction.

3280. Misbranding of Liv and Scrub. U. S. v. 70 Jars, etc. (F. D. C. No. 29376. Sample Nos. 88167-K, 88168-K.)

LIBEL FILED: June 30, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about April 4 and May 4, 1950, by Gene Salee, Inc., from Los Angeles, Calif.

PRODUCT: 70 2-ounce jars and 40 4-ounce jars of *Liv* and 67 2-ounce jars and 60 4-ounce jars of *Scrub* at Denver, Colo. Each jar contained a circular entitled "Liv."

RESULTS OF INVESTIGATION: On display in the store of the consignee, together with the articles, were a number of leaflets and a display placard entitled "Thrilling New Complexion Aid" and a display placard entitled "Healing Ointment On Market As Cosmetic."

The leaflets were given to customers and were available to anyone coming to the counter. Information obtained during the investigation indicated that the *Liv* consisted essentially of ichthammol, bentonite, glycerin, and water, and that the *Scrub* consisted essentially of almond meal, honey, cholestrin, and water.

Label, In Part: (Jars) "Liv Beautifies Blemished Complexion" and "Scrub Cleanses Pores Stimulates Drab Skin."

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements on the jar labels and in the circular contained in the jars were false and misleading

since the statements represented and suggested that the articles were effective in the removal of skin blemishes, blotches, and pimples, whereas the articles were not effective for such purposes; and certain statements in the leaflets and on the placards on display with the articles were false and misleading since they represented and suggested that the articles were efficacious in the removal of skin blemishes and blotches, pimples, pitted skin, acne, and edema with concomitant puffiness of face, and, further, that the articles were efficacious to promote rapid healing of burns, whereas the articles were not effective for such purposes.

The articles were misbranded when introduced into, and while in, interstate commerce by reason of the statements on the labels and in the circular referred to above, and were misbranded while held for sale after shipment in interstate commerce by reason of the statements described above in the leaflets

and on the placards on display with the articles.

resposition: October 24, 1950. The shipper of the products having consented to the entry of a decree, judgment of condemnation was entered. Thereafter, the labeling of the product was destroyed, after which the products were disposed of by the marshal in accordance with the law.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3261 TO 3280

PRODUCT

PRODUCTS			
N. J. No	N. J. No.		
etris-Helonias Compound,	Iron Quota tablets, Missouri		
Elixir 3268	Brand 3271		
eca nuts 3274	Juniper berries 3273		
thritis, remedy for 3270, 3279	Laxative without required warn-		
otanical Laxative Compound,	ing statements 3269		
Rutang 3279	Liv 3280		
ncer, remedy for 3278	Live Spot vitamin E capsules,		
trate of magnesia 3275	Missouri Brand 3271		
tru-Mix 3270	1 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
cillana bark 3272	Mineral water, Veronica 3277		
old and grippe remedy, Hollis 3269	Missouri Brand Iron Quota tab-		
mbisul tablets 3266	lets, Missouri Brand Golden		
smetics (subject to the drug	Seal Plus Fennel tablets, and		
provisions of the Act) 3280	Missouri Brand Live Spot		
esoxyn Hydrochloride tablets 3266			
evices 3276			
exedrine Sulfate tablets 3262-3265	32.3		
ethylstilbestrol tablets 3263-3265			
lixir Aletris-Helonias Com-	Pentobarbital sodium capsules 3265		
pound 3268			
olden Seal Plus Fennel tablets,	Rheumatism, remedy for 3270, 3279		
Missouri Brand 3271			
ett's Serum 3278	promise a supplementation		
ollis cold and grippe remedy,	Liniment, and Rutang tab-		
Hollis Indian herbs, and	lets 3279		
Hollis tonic for men 3269	Scrub 3280		

3279. Misbranding of Rutang Botanical Laxative Compound, Rutang Super White Liniment, and Rutang tablets. U. S. v. 41 Bottles, etc. (F. D. C. Sample Nos. 81860-K to 81862-K, incl.)

LIBEL FILED: July 21, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about May 16 and 26 and June 5, 1950, from Columbus. Ohio.

PRODUCT: 41 1-pint bottles of Rutang Botanical Laxative Compound, 71 1pint bottles of Rutang Super White Liniment, and 36 100-tablet bottles of Rutang tablets at Miami, Fla., in possession of the Vita Health Co., together with a number of circulars entitled "Rutang Price List No. 11."

Analysis showed that the Rutang Botanical Laxative Compound was an aqueous solution of plant extractives, including emodin; that the Rutang Super White Liniment was an aqueous ammoniacal suspension of turpentine and camphor; and that the Rutang tablets contained aspirin and calcium succinate.

RESULTS OF INVESTIGATION: The circulars described above were printed locally and were given to customers of the consignee.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circular were false and misleading. The statements represented and suggested that the Rutang Botanical Laxative Compound was effective in the treatment of gastritis; that it was effective for providing strength and vitality, for making one feel better, for relieving pains, for curing the human body, and for preventing suffering; and that the Rutang Super White Liniment and the Rutang tablets were effective in the treatment of rheumatism, neuritis, and arthritis. The articles were not effective treatments for the conditions stated and implied.

The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 12, 1950. Default decree of forfeiture and destruction.

3280. Misbranding of Liv and Scrub. U. S. v. 70 Jars, etc. (F. D. C. No. 29376. Sample Nos. 88167-K, 88168-K.)

LIBEL FILED: June 30, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about April 4 and May 4, 1950, by Gene Salee, Inc., from Los Angeles, Calif.

PRODUCT: 70 2-ounce jars and 40 4-ounce jars of Liv and 67 2-ounce jars and 60 4-ounce jars of Scrub at Denver, Colo. Each jar contained a circular entitled "Liv."

RESULTS OF INVESTIGATION: On display in the store of the consignee, together with the articles, were a number of leaflets and a display placard entitled "Thrilling New Complexion Aid" and a display placard entitled "Healing Ointment On Market As Cosmetic."

The leaflets were given to customers and were available to anyone coming to the counter. Information obtained during the investigation indicated that the Liv consisted essentially of ichthammol, bentonite, glycerin, and water, and that the Scrub consisted essentially of almond meal, honey, cholestrin,

LABEL, IN PART: (Jars) "Liv Beautifies Blemished Complexion" and "Scrub Cleanses Pores Stimulates Drab Skin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the jar labels and in the circular contained in the jars were false and misleading

since the statements represented and suggested that the articles were effective in the removal of skin blemishes, blotches, and pimples, whereas the articles were not effective for such purposes; and certain statements in the leaflets and on the placards on display with the articles were false and misleading since they represented and suggested that the articles were efficacious in the removal of skin blemishes and blotches, pimples, pitted skin, acne, and edema with concomitant puffiness of face, and, further, that the articles were efficacious to promote rapid healing of burns, whereas the articles were not effective for such purposes.

The articles were misbranded when introduced into, and while in, interstate commerce by reason of the statements on the labels and in the circular referred to above, and were misbranded while held for sale after shipment in interstate commerce by reason of the statements described above in the leaflets and on the placards on display with the articles.

DISPOSITION: October 24, 1950. The shipper of the products having consented to the entry of a decree, judgment of condemnation was entered. Thereafter, the labeling of the product was destroyed, after which the products were disposed of by the marshal in accordance with the law.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3261 TO 3280

PRODUCTS

N. J. No.	N. J. No.
Aletris-Helonias Compound,	Iron Quota tablets, Missouri
Elixir 3268	Brand 3271
Areca nuts 3274	Juniper berries 3273
Arthritis, remedy for 3270, 3279	Laxative without required warn-
Botanical Laxative Compound,	ing statements 3269
Rutang 3279	Liv 3280
Cancer, remedy for 3278	Live Spot vitamin E capsules,
Citrate of magnesia 3275	Missouri Brand 3271
Citru-Mix 3270	Magnesia, citrate of 3275
Cocillana bark 3272	Mineral water, Veronica 3277
Cold and grippe remedy, Hollis 3269	Missouri Brand Iron Quota tab-
Combisul tablets 3266	lets, Missouri Brand Golden
Cosmetics (subject to the drug	Seal Plus Fennel tablets, and
provisions of the Act) 3280	Missouri Brand Live Spot
Desoxyn Hydrochloride tablets 3266	vitamin E capsules 3271
Devices 3276	Neuritis, remedy for 3270, 3279
Dexedrine Sulfate tablets 3262-3265	Orrisroot 3273
Diethylstilbestrol tablets 3263-3265	P-V-F-M 3261
Elixir Aletris-Helonias Com-	Pentobarbital sodium capsules 3265
pound 3268	Prophylactics 3276
Golden Seal Plus Fennel tablets,	Rheumatism, remedy for 3270, 3279
Missouri Brand 3271	Rutang Botanical Laxative Com-
Hett's Serum 3278	pound, Rutang Super White
Hollis cold and grippe remedy,	Liniment, and Rutang tab-
Hollis Indian herbs, and	lets 3279
Hollis tonic for men 3269	Scrub 3280

N.	J. No.	N.	J. No.
Seconal Sodium capsules	326 6	Tonic for men, Hollis	32 69
Special tablets	3267	Triple Sulfonamides tablets	3265
Sulfadiazine tablets	3264	Veronica mineral water	3277
and sodium bicarbonate tab-		Veterinary preparation	3261
lets	3263	Vitamin preparations	3271
Super White Liniment, Rutang	3279	Yellow dock root	3273
Thyroid tablets	3264		
SHIPPERS, MANUF	ACTUR	ERS, AND DISTRIBUTORS	
N.	J. No.	· N.	J. No.
Binford, R. A.:		Kordel, Lelord:	
Dexedrine Sulfate tablets, sul-		Missouri Brand Iron Quota	
fadiazine tablets, thyroid		tablets, Missouri Brand	
tablets, and diethylstilbestrol		Golden Seal Plus Fennel tab-	
tablets	3264	lets, and Missouri Brand	
Boyett, W. M.:		Live Spot vitamin E cap-	
diethylstilbestrol tablets, Dex-		sules	3271
edrine Sulfate tablets, and		Mark Halsey Drug Stores:	
sulfadiazine and sodium bi-		Dexedrine Sulfate tablets	3262
carbonate tablets	3263	Martin, I. W., Dr.:	
Cole, F. W.:		P-V-F-M	3261
Veronica mineral water	3277	Martin, William E., Co.:	
Dean Rubber Mfg. Co.:		Areca nuts	3274
prophylactics	3276	Medical Arts Pharmacy. See	
Dickson, W. C.:		Dickson, W. C.	
Desoxyn Hydrochloride tab-		Moore, M. O., Dr.:	
lets. Combisul tablets, and		Hett's Serum	3278
Seconal Sodium capsules	3266	Neels, C. E.:	
Duncan, R. H.:		Triple Sulfonamides tablets,	
diethylstilbestrol tablets, Dex-		Dexedrine Sulfate tablets,	
edrine Sulfate tablets, and		diethylstilbestrol tablets,	
sulfadiazine and sodium bi-		and pentobarbital sodium	
carbonate tablets	3263	capsules	3265
Evans, W. W.:		Neels Drugs. See Neels, C. E.	
Dexedrine Sulfate tablets, sul-		Nelson Laboratories:	
fadiazine tablets, thyroid		P-V-F-M	3261
tablets, and diethylstilbestrol		Nu-Way Corp.:	
tablets	3264	Citru-Mix	3270
Evans Drug Co., Inc.:		Olmstead, D. M., Laboratories:	
diethylstilbestrol tablets, Dex-		Special tablets	3267
edrine Sulfate tablets, and		Parke, Davis & Co.:	
sulfadiazine and sodium bi-		Elixir Aletris-Helonias Com-	
carbonate tablets	3263	pound	3268
Gene Salee, Inc.:		Purswell, A. D.:	
Liv and Scrub	3280	Dexedrine Sulfate tablets	3262
Hollis, Thomas, Co.:		Reynolds, W. C.:	
Hollis cold and grippe remedy,		Dexedrine Sulfate tablets	3262
Hollis Indian herbs, and		Richards, J. C.:	
Hollis tonic for men	3269	Dexedrine Sulfate tablets	3262

Robinson Laboratories:	. J. No.	Vita Health Co.:
citrate of magnesia	3275	Rutang Botanical Laxative
Roholt, O. A., Sr.:		Compound, Rutang Super
Desoxyn Hydrochloride tab-		White Liniment, and Rutang
lets, Combisul tablets, and		tablets 3279
Seconal Sodium capsules	3266	Wyatt, R. H.:
Thomas Hollis Co. See Hollis,		diethylstilbestrol tablets, Dex-
Thomas, Co.		edrine Sulfate tablets, and
Veronica Sales Co., Ltd.:		sulfadiazine and sodium bi-
Veronica mineral water	3277	carbonate tablets 3263

REPUBLICATION OF

the first of the second second second

THE RESIDENCE OF THE PROPERTY OF THE PROPERTY

COST AND ADMINISTRATION OF THE PARTY OF THE

may again a dhomang Utils



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs

Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3281-3300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs. Washington, D. C., March 1, 1951.

CONTENTS*

	P	age		Page
Dru	igs actionable because of failure		Drugs actionable because of false	
	to bear adequate directions or		and misleading claims	265
	warning statements	256	Drugs for human use	265
Dru	ig actionable because of con-		Drugs for veterinary use	269
	tamination with filth	262	Index	272
Dru	igs and devices actionable be-			
	cause of deviation from official			
	or own standards	262		

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3283-3287; omission of, or unsatisfactory, ingredients statements, Nos. 3281, 3283, 3299, 3300; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3281-3287, 3294; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3281, 3283, 3284, 3294; cosmetic, actionable under the drug provisions of the Act, see No. 3297 (Dr. Shokunbi's F-62 Herbal Hair Growing Aid).

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3281. Misbranding of diethylstilbestrol tablets, sulfadiazine tablets, and Dexedrine Sulfate tablets. U. S. v. Clifford H. McDaniel (City Drug Co.). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 29419. Sample Nos. 27080-K, 61049-K, 61644-K.)
- INFORMATION FILED: June 7, 1950, Western District of Kentucky, against Clifford H. McDaniel, trading as the City Drug Co., Fulton, Ky.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania, into the State of Kentucky, of quantities of diethylstilbestrol tablets, sulfadiazine tablets, and Dexedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about September 13, 28, and 29, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine* tablets and *Devedrine Sulfate tablets* failed to bear labels containing the common or usual name of the drugs; and, Section 502 (f) (2), the labeling of the *sulfadiazine tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: October 23, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$150.
- 3282. Misbranding of diethylstilbestrol tablets, Dexedrine Sulfate tablets, Benzedrine Sulfate tablets, sulfadiazine tablets, and thyroid tablets. U. S. v. Albert G. Wilson, Frank J. Kolb, Jr., and Thomas P. Turnbow. Pleas of nolo contendere. Fines of \$100 against defendant Wilson, \$100 against defendant Kolb, and \$50 against defendant Turnbow. (F. D. C. No. 29426. Sample Nos. 27072-K, 61047-K, 61728-K to 61730-K, incl.)
- Information Filed: June 28, 1950, Western District of Kentucky, against Albert G. Wilson, a partner in the partnership of Wilson & Little Pharmacy, Mayfield, Ky., and against Frank J. Kolb, Jr., and Thomas P. Turnbow, pharmacists for the partnership.
- INTERSTATE SHIPMENT: From the States of Indiana, Pennsylvania, and Missouri, into the State of Kentucky, of quantities of diethylstilbestrol tablets, Devedrine Sulfate tablets, Benzedrine Sulfate tablets, sulfadiazine tablets, and thyroid tablets.
- ALLEGED VIOLATION: While the drugs were being held for sale after shipment in interstate commerce, defendant Wilson caused various quantities of the diethylstilbestrol tablets and Dexedrine Sulfate tablets to be repacked and sold without a prescription on or about September 28, 1949; defendant Kolb caused various quantities of the Benzedrine Sulfate tablets and sulfadiazine tablets to be repacked and sold without a prescription on or about September

25, 1949; and defendant Turnbow caused a quantity of *thyroid tablets* to be repacked and sold without a prescription on or about September 26, 1949. It was alleged also that such acts of the defendants resulted in the repackaged drugs being misbranded.

- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged sulfadiazine tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- DISPOSITION: October 23, 1950. Pleas of nolo contendere having been entered on behalf of the defendants, the court imposed fines of \$100 against defendant Wilson, \$100 against defendant Kolb, and \$50 against defendant Turnbow.
- 3283. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Stephen E. Piotrowski (Stephen E. Piotrowski Pharmacy). Plea of guilty. Fine, \$300. (F. D. C. No. 29454. Sample Nos. 60660-K to 60664-K, incl.)
- Information Filed: September 11, 1950, Eastern District of Wisconsin, against Stephen E. Piotrowski, trading as the Stephen E. Piotrowski Pharmacy, Milwaukee, Wis.
- Interstate Shipment: From the States of Indiana and Pennsylvania, into the State of Wisconsin, of quantities of Seconal Sodium capsules and Benzedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about September 28 and 30 and October 1, 13, and 18, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules and tablets to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

- DISPOSITION: November 27, 1950. A plea of guilty having been entered, the court imposed a fine of \$300.
- 3284. Misbranding of Seconal Sodium capsules. U. S. v. Edwin E. Wiegand. Plea of nolo contendere. Fine of \$1,000 on count 1; sentence suspended on remaining three counts of information and defendant placed on probation for 1 year. (F. D. C. No. 29450. Sample Nos. 41977-K, 41978-K, 59949-K, 59957-K.)

Information Filed: September 6, 1950, Eastern District of Wisconsin, against Edwin E. Wiegand, Milwaukee, Wis.

ALLEGED VIOLATION: The defendant, on or about March 17 and 21, 1950, caused the introduction into interstate commerce at Milwaukee, Wis., for delivery to Chicago, Ill., of quantities of Seconal Sodium capsules which were misbranded. The defendant also made two over-the-counter sales of Seconal Sodium capsules.

The capsules had been shipped in interstate commerce from Indianapolis, Ind., to Milwaukee, Wis., and while held for sale after such shipment, the capsules were repacked by the defendant and sold without a physician's prescription, which acts of the defendant resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the capsules bore no labeling containing directions for use.

- DISPOSITION: December 11, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$1,000 on count 1, suspended the imposition of sentence on the remaining three counts of the information, and placed the defendant on probation for 1 year.
- 3285. Misbranding of Nembutal-C tablets, Nembutal Sodium capsules, Benzedrine Sulfate tablets, and Dexedrine Sulfate tablets. U. S. v. Pitman-Wilson Co. and Herman N. Amick. Pleas of nolo contendere. Fines of \$300 against company and \$150 against individual. (F. D. C. No. 29468. Sample Nos. 52537-K, 52950-K, 52956-K, 52957-K, 72281-K, 72378-K.)
- Information Filed: October 10, 1950, Southern District of Indiana, against the Pitman-Wilson Co., a corporation, Rushville, Ind., and Herman N. Amick, secretary-treasurer of the corporation.
- INTERSTATE SHIPMENT: From the States of Ohio, Pennsylvania, and Illinois, into the State of Indiana, of quantities of Nembutal-C tablets, Nembutal Sodium capsules, Benzedrine Sulfate tablets, and Dexedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about September 13 and December 28, 1949, and January 4 and 5, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the repackaged Nembutal-C tablets and Nembutal Sodium capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the labels of the repackaged Nembutal-C tablets and Nembutal Sodium capsules failed

- to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."
- DISPOSITION: November 10, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$300 against the company and a fine of \$150 against the individual.
- 3286. Misbranding of Nembutal Sodium capsules. U. S. v. B. T. Smith Co., Inc., Bernard T. Smith, Louis Hergenrather, 3d, and Charles E. Spigelmire. Pleas of guilty. Fine of \$25, plus costs, against each defendant. (F. D. C. No. 29464. Sample Nos. 2390-K to 2392-K, incl., 67210-K, 67214-K.)
- INFORMATION FILED: November 15, 1950, District of Maryland, against B. T. Smith Co., Inc., Baltimore, Md., and against Bernard T. Smith, president, Charles E. Spigelmire, vice president, and Louis Hergenrather, 3d, secretary-treasurer, of the corporation.
- INTERSTATE SHIPMENT: From the State of Illinois into the State of Maryland, of quantities of Nembutal Sodium, capsules.
- ALLEGED VIOLATION: On or about January 13, 20, and 30, and February 3 and 7, 1950, while the drug was being held for sale after shipment in interstate commerce, the defendants caused quantities of the capsules to be repacked and sold without a physician's prescription, which acts resulted in the capsules being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations, designated as, habit forming; and the labeling of the repacked capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions for use "One capsule at bedtime," borne on the labeling of the repackaged capsules, were not adequate directions for use.

- DISPOSITION: December 8, 1950. Pleas of guilty having been entered, the court imposed a fine of \$25, plus costs, against each of the four defendants.
- 3287. Misbranding of phenobarbital tablets. U. S. v. Matthias Prescription Pharmacy, Inc., and William C. Matthias. Pleas of guilty. Fine of \$20 against each defendant. (F. D. C. No. 29475. Sample Nos. 58158-K, 58164-K, 58165-K, 58492-K.)
- INFORMATION FILED: November 1, 1950, District of Arizona, against Matthias Prescription Pharmacy, Inc., Tucson, Ariz., and William C. Matthias, president of the corporation.
- INTERSTATE SHIPMENT: From the State of California into the State of Arizona, of a number of tablets containing 1½ grains and ½ grain of phenobarbital.
- ALLEGED VIOLATION: On or about July 21 and August 5, 22, and 23, 1949, while the tablets were being held for sale after shipment in interstate commerce, the defendants caused a number of the tablets to be repacked and sold without a physician's prescription, which acts of the defendants resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and, the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions for use "One tablet at bedtime" and "One tablet three times a day after meals," borne on the labeling of the repackaged tablets, were not adequate directions for use.

DISPOSITION: November 15, 1950. Pleas of guilty having been entered, the court imposed a fine of \$20 against each defendant.

3288. Misbranding of cancer cure. U. S. v. 2 Bottles, etc. (F. D. C. No. 29080. Sample No. 49689–K.)

LIBEL FILED: April 19, 1950, District of Colorado.

ALLEGED SHIPMENT: The Hoxsey Cancer Clinic shipped from Dallas, Tex., to Denver, Colo., on or about March 28, 1950, two pint bottles of a product labeled, in part: "From Hoxsey Cancer Clinic, 4507 Gaston Ave., Dallas, Texas. To Regular Concentrate add enough water to make 1 Gal. Shake Well." Linwood E. Downs transported from the Hoxsey Cancer Clinic, Dallas, Tex., to Denver, Colo., during or about September 1948, 1 unlabeled jar containing approximately 2 ounces of a yellow powder.

Approximately 90 booklets which related to the drug and which were entitled "Hoxsey Cancer Clinic Specializing in Cancer" were shipped also from Dallas Tex., from the Hoxsey Cancer Clinic.

PRODUCT: Analysis of a sample of the "Regular Concentrate" showed that it was a dark brown, opaque liquid having a bitter taste suggesting cascara, and having the odor and taste of licorice, and that it consisted essentially of an aqueous solution of potassium iodide, licorice, and other plant extractives, including (probably) cascara.

Examination of the yellow powder showed that it consisted principally of arsenious sulfide, arsenious oxide, and aluminum silicate.

Nature of Charge: Misbranding, Section 502 (a), the labeling of the article, namely, the above-mentioned booklets, contained statements which represented and suggested that the articles were effective in the treatment and cure of cancer, whereas the articles were not effective for such purposes; and, Section 502 (f) (2), the labeling of the yellow powder failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, or application, in such manner and form as are necessary for the protection of the user. The articles were misbranded when introduced into, and while in, interstate commerce, and while held for sale after receipt in interstate commerce.

DISPOSITION: June 1, 1950. Default decree of condemnation. The court ordered that the articles of drugs and booklets be released to the Food and Drug Administration.

3289. Misbranding of Dr. Morse's Indian Root pills and Comstock's Dead Shot worm pellets. U. S. v. 469 Packages, etc. (F. D. C. No. 26044. Sample Nos. 2075-K, 2076-K.)

LIBEL FILED: December 3, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about November 4 and December 30, 1947, and January 27, March 22 and 30, June 14, and September 7, 1948, by W. H. Comstock Co., Ltd., from Morristown, N. Y.

PRODUCT: 469 packages of Dr. Morse's Indian Root pills and 142 packages of Comstock's Dead Shot worm pellets at Washington, D. C.

LABEL, IN PART: (Package) "Dr. Morse's Indian Root Pills (Improved) * * * Active Ingredients: Aloes, Mandrake, Gamboge Jalap, Cayenne Pepper Contents 40 Pills" and "Comstock's Dead Shot Worm Pellets * * * Contains 10 Pellets * * * Active Ingredients Ext. Pepo Spigelia (Pink Root)."

NATURE of CHARGE: Dr. Morse's Indian Root pills. Misbranding, Section 502 (a), the following statements in the leaflet entitled "The Joy of Living" accompanying the article were false and misleading since the article was not capable of fulfilling the promises of benefit stated and implied by such statements: "The manufacturers of Dr. Morse's Indian Root Pills have compounded this laxative to assist man when he overindulges in eating or drinking, and through the lack of proper exercise, by helping to renew his interest in life * * * It pays to be regular * * * We moderns eat, drink or smoke too much, eat too quickly, do not have sufficient sleep-too little fresh air and exercise. As a result we become constipated. You should watch for these signs: Sick headache, dizziness, sallow skin, fuzzy tongue * * * and that 'gone' tired feeling. Now is the time to get out your box of Dr. Morse's Indian Root Pills (Improved) to get that bowel movement to give you that feeling of pep and to renew your interest in life. Bad Breath-Fuzzy Coated Tongue—Bad Taste in the Mouth—Due to Temporary Constipation—When you feel or see these signs due to temporary constipation, take one or two Dr. Morse's Indian Root Pills (Improved) before and after meals and two to four Pills before going to bed. Continue as required * * * As you grow better, and the movements become regular, take a smaller number of pills until you feel no further need of them * * * Continue until the movements become regular." Further misbranding, Section 502 (a), the designation "Indian Root" in the name of the article was false and misleading since Indians did not make use of this combination of drugs, and the ingredients, aloe and cayenne pepper, are not roots and are not obtained from roots; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe methods and duration of administration in such manner and form as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to warn that frequent or continued use of the article, or its use in accordance with the following directions appearing in its labeling, may result in dependence upon a laxative to move the bowels: (Package) "Adults-1 to 2 Pills before and after meals and 2 to 4 at bed time" and (leaflet) "Take one to two Dr. Morse's Indian Root Pills (Improved) before and after meals and two to four before going to bed. Continue as required. * * * Constipation * * * Grownups suffering from this trouble should take one to two Dr. Morse's Indian Root Pills (Improved) Before and after each meal and two to four pills before going to bed. Continue until movements become regular or until you have no further need of them. Continue as required."

Comstock's Dead Shot worm pellets. Misbranding, Section 502 (a), the designation on the container and leaflet "Comstock's Dead Shot Worm Pellets for Round and Pin Worms," the statements on the container "This medicine helps to expel the worms," and the statements in the accompanying leaflet "If you are not sure that the worms and their eggs have been removed the same dose should be taken two weeks after the first dose. Thread Worms—In addition to the internal treatment, it will be necessary in the case of Thread Worms to use an enema * * * Delicate, underweight, or frail users should decrease the dose but continue the remedy three or four nights" were false and misleading since the article was not effective for the removal of round worms, pin worms, or thread worms.

DISPOSITION: W. H. Comstock Co., Ltd., claimant, having petitioned for the removal of the case to the Southern District of New York and the Government having consented, an order was entered on January 11, 1949, directing such removal. On May 3, 1950, the claimant having failed to file an answer to the libel, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3290. Adulteration and misbranding of Geo-Mineral. U. S. v. 75 Bottles * * *. (F. D. C. No. 27042. Sample No. 41028-K.)

LIBEL FILED: On or about April 15, 1949, District of Montana.

ALLEGED SHIPMENT: On or about January 27, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 75 3-ounce bottles of Geo-Mineral at Great Falls, Mont., in possession of the Pay Less Drug Store.

Label, In Part: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated in interstate commerce.

Misbranding, Section 502 (a), the statements appearing on a placard on display in the store of the consignee, "Geo-Mineral — Stomach Ailments — Weak Kidneys — Rheumatic Pains — Arthritis — Neuritis," were false and misleading since the article was not effective in the treatment of these conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 27, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3291. Adulteration and misbranding of Gothestrone. U. S. v. Gotham Pharmaceutical Co., Inc., and Max Grossman. Plea of guilty for corporation and plea of nolo contendere for individual. Fine of \$1,000 against corporation. Sentence of 1 year in penitentiary against individual; sentence suspended and individual placed on probation for 1 year. (F. D. C. No. 28155. Sample Nos. 4736-K, 10057-K.)

INFORMATION FILED: April 28, 1950, Eastern District of New York, against the Gotham Pharmaceutical Co., Inc., Brooklyn, N. Y., and Max Grossman, president of the corporation.

ALLEGED SHIPMENT: On or about June 2 and 22, 1949, from the State of New York into the States of Massachusetts and New Jersey.

LABEL, IN PART: "Gothestrone Macro-crystalline Aqueous Suspension of Natural Estrogenic Hormones."

NATURE of CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was represented to be suitable and appropriate for intramuscular use, which use requires a sterile product, whereas the article was not suitable and appropriate for such use since it was not sterile but was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the labeling of the article contained statements which represented and suggested that the article would be suitable and appropriate for intramuscular use, which statements were false and misleading since the article was not suitable and appropriate for such use.

DISPOSITION: October 19, 1950. A plea of guilty having been entered on behalf of the corporation and a plea of nolo contendere on behalf of the individual, the court imposed a fine of \$1,000 against the corporation and a sentence of 1 year in the penitentiary against the individual. The sentence against the individual was suspended, and he was placed on probation for 1 year.

3292. Adulteration of dextro-amphetamine phosphate and dextro-amphetamine sulfate. U. S. v. 1 Drum, etc. (F. D. C. No. 29661. Sample Nos. 73632-K, 73633-K, 73635-K.)

LIBEL FILED: On or about July 27, 1950, District of New Jersey.

ALLEGED SHIPMENT: On or about April 21 and May 8 and 16, 1950, by Tru-Synthetics, Inc., from Long Island City, N. Y.

PRODUCT: 1 drum containing 13¼ pounds of dextro-amphetamine phosphate and 1 drum containing 12½ pounds, and 1 drum containing 15 pounds, of dextro-amphetamine sulfate.

Label, IN Part: "Batch No. 18 Control No. P62 Dextro-Amphetamine Phosphate" and "Batch No. 18 Control No. SD61 Dextro-Amphetamine Sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from, and their quality fell below, that which they were represented to possess. The product labeled "Dextro-Amphetamine Phosphate" was represented to consist of approximately 100 percent of that ingredient, whereas it contained approximately only 70 percent of dextro-amphetamine phosphate and 30 percent of levo-amphetamine phosphate; and the product labeled "Dextro-Amphetamine Sulfate" was represented to consist of approximately 100 percent of that ingredient, whereas it contained approximately only 70 percent of dextro-amphetamine sulfate and 30 percent of levo-amphetamine sulfate.

Disposition: October 17, 1950. Tru-Synthetics, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the products be released under bond for removal of all adulterated ingredients and for reprocessing, so that the products could be brought into compliance with the law.

3293. Adulteration of dl-amphetamine sulfate. U. S. v. 1 Drum * * *.

(F. D. C. No. 29406. Sample No. 42999-K.)

LIBEL FILED: July 27, 1950, Northern District of Illinois.

928022--51----2

ALLEGED SHIPMENT: On or about April 28, 1950, by Tru-Synthetics, Inc., from Long Island City, N. Y.

PRODUCT: 1 drum containing 71/2 pounds of dl-amphetamine sulfate at Chicago, Ill.

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess since the article contained approximately 35 percent of dextro-amphetamine sulfate and 65 percent of levo-amphetamine sulfate, whereas dl-amphetamine sulfate contains equal proportions of dextro- and levo-amphetamine sulfate.

DISPOSITION: November 8, 1950. Default decree of condemnation and destruction.

3294. Adulteration and misbranding of milk of magnesia tablets. U. S. v. 110
Cartons * * *. (F. D. C. Nos. 29859, 29860. Sample Nos. 77626-K,
78103-K, 78105-K.)

LIBELS FILED: November 1, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of October 13, 1949, and September 15, 1950, by the Rey Mfg. Co., from Evansville, Ind.

PRODUCT: Milk of magnesia tablets. 110 cartons, each containing 12 100-tablet bottles, and 24 cartons, each containing 24 250-tablet bottles, at St. Louis, Mo.

LABEL, IN PART: (Bottle) "American Lady Milk of Magnesia Tablets" or "TMC Milk of Magnesia Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (d), aspirin tablets had been substituted in part for milk of magnesia tablets.

Misbranding (American Lady brand), Sections 502 (b) (1) and (2), the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: November 27, 1950. Default decrees of condemnation and destruction.

3295. Adulteration and misbranding of Bactra-Tycin ointment. U. S. v. 41

Jars * * *. (F. D. C. No. 29553. Sample No. 82238-K.)

LIBEL FILED: On or about September 1, 1950, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about August 2, 1950, by Wallace Laboratories, Inc., from New Brunswick, N. J.

PRODUCT: 41 jars of bactra-tycin ointment at Huntington, W. Va.

Label, IN Part: "55 Grams Bactra-Tycin Ointment * * * Each Gram Contains 1,000 MMG. Tyrothricin (Gramicidin Fraction Not Less Than 200 MMG.)."

NATURE of CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 1,000 milli-milligrams, (micrograms) of tyrothricin per gram.

Misbranding, Section 502 (a), the label statement "Each Gram Contains 1,000 MMG. Tyrothricin" was false and misleading as applied to an article which contained less than that amount of tyrothricin.

DISPOSITION: October 24, 1950. Default decree of condemnation and destruction.

3296. Adulteration and misbranding of clinical thermometers. U. S. v. 22

Boxes * * * (F. D. C. No. 29834. Sample No. 80143-K.)

LIBEL FILED: October 18, 1950, District of New Hampshire.

Alleged Shipment: On or about August 18 and September 8, 1950, by the Consolidated Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 22 boxes each containing 1 dozen *clinical thermometers* at Manchester, N. H. Examination of 24 thermometers showed that 2 did not meet the standard of accuracy declared in the labeling; that 1 failed to meet the test for retreating index; and that 5 showed loss of pigment.

Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess, namely, "Clinical Fever Thermometers" and "correct within plus or minus 2/10° F. at 98° and 102° F. and 3/10° F. at 106° F."

Misbranding, Section 502 (a), the following statement in the labeling of the article was false and misleading as applied to an article which would not give accurate readings: "This certifies that the thermometer bearing the above identification number has been examined and tested and is correct within plus or minus 2/10° F. at 98° and 102° F. and 3/10° F. at 106° F. or its equivalent in Centigrade scale."

DISPOSITION: November 27, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3297. Misbranding of Dr. Shokunbi's F-219 Asthma Aid, Dr. Shokunbi's Tree of Life F-218, Dr. Shokunbi's F-62 Herbal Hair Growing Aid, and Dr. Shokunbi's F-214 Nervine. U. S. v. Samuel P. Shokunbi (African Herb & Chemical Co.). Plea of not guilty. Tried to the court and jury; verdict of guilty. Defendant fined \$9,000, plus costs, and sentenced to 9 years in prison. (F. D. C. No. 28158. Sample Nos. 19324-K to 19327-K, incl., 27993-K, 52066-K, 53434-K, 61822-K, 62025-K.)

INFORMATION FILED: August 8, 1950, Western District of Tennessee, against Samuel P. Shokunbi, trading as the African Herb & Chemical Co., Memphis, Tenn.

ALLEGED SHIPMENT: On or about February 23, March 3, 7, and 15, and October 18, 1949, from the State of Tennessee into the States of Ohio, Mississippi, Alabama, and Missouri.

LABEL, IN PART: "Dr. Shokunbi's F-219 Asthma Aid * * * This tonic contains the following herbs: Hore Hound, Mullen Leaves, Peppermint Leaves, Wild Plum Bark, Wild Cherry Bark, Lemon, Peach Leaves, Colts Foot, Boneset, Pure Honey, Catnip, Skull Cap, Vavain, Corriander Seed."

"Dr. Shokunbi's Tree of Life F-218 General Tonic for Men and Women * * * Yellow Dock, Burdock Root, Poke Root, Buchu Leaves, Peppermint Leaves, May Apple, Juniper Berries, Black Snake Root, Samson Root, Wild Plum Bark, Wild Cherry Bark, Skull Cap, Fever Few, Lady Slipper, Senna, Figs."

"Dr. Shokunbi's F-62 Herbal Hair Growing Aid * * * Ingredients: Sage Leaves Extract, Jaborandie Extract, Yellow Dock Root Oil, Hair Cap Moss, Olive Oil, Fresh Eggs, Salicylic Acid-Preservative."

^{*}See also Nos. 3288-3291, 3295, 3296.

"Dr. Shokunbi's F-214 Nervine * * * Ingredients: Blue Skull Cap. Valarin, Catnip, Lady Slipper, Corriander Seed, Capsicum."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels, in a pamphlet entitled "Universal Tabloid," and on a circular entitled "Why Use Chemical Drugs," accompanying certain shipments of *Dr. Shokunbi's Tree of Life F-218*, were false and misleading. These statements represented and suggested:

That the *Dr. Shokunbi's F-219 Asthma Aid* when used as directed would be efficacious for the treatment of asthma, chronic bronchitis, hay fever, and persistent coughs with congestion and irritation of the throat, and that the product was a tonic;

That the *Dr. Shokunbi's Tree of Life F-218* when used as directed would be efficacious in the treatment of high blood pressure, low blood pressure, kidney disease, bladder disease, rheumatic pain, gas on stomach, run-down condition, nervousness, cough due to cold, chronic bronchitis, asthma, arthritis, backache, change of life, lumbago, and conditions implied by the abbreviation, etc., and that it was a general tonic for men and women;

That the Dr. Shokunbi's F-62 Herbal Hair Growing Aid when used as directed would be efficacious to aid the growth of hair; and

That the Dr. Shokunbi's F-214 Nervine when used as directed would be efficacious in the treatment of nervous debility, hysteria, melancholia, neurasthenia, overwork, brain fatigue, and conditions implied by the abbreviation, etc., and that it was a general tonic.

The products when used as directed would not be effective for the purposes claimed.

DISPOSITION: A plea of not guilty having been entered on behalf of the defendant, the case came on for trial before the court and jury on October 30, 1950. The trial was concluded on November 1, 1950, at which time the jury returned a verdict of guilty against the defendant. On the latter date, the court imposed a fine of \$9,000, plus costs, and a sentence of 9 years in prison against the defendant.

3298. Misbranding of mineral water. U. S. v. 15 Cases, etc. (F. D. C. No. 29714. Sample No. 3051–K.)

LIBEL FILED: August 28, 1950, District of Columbia.

PRODUCT: 15 cases, each containing 1 dozen 1-pint bottles, of mineral water in interstate commerce in the District of Columbia in the possession of R. & S. Nutrients, Inc., together with 38 packages, each containing 240 booklets entitled "Mineral Water from the Mile Deep Maple Well J. L. Rogers, D. C., N. D. Price 25¢."

Examination indicated that the product consisted of a solution of calcium chloride, magnesium chloride, sodium chloride and small proportions of other mineral salts, including potassium, iron, and iodine compounds that possess a negligible radio-activity.

LABEL, IN PART: "Mile Deep Natural Mineral Water from Maple, Ontario."

NATURE OF CHARGE: Misbranding, Section 502 (a) certain statements in the booklet were false and misleading since the article would not accomplish the results stated and implied. The statements represented and suggested that a spoonful daily of the article would provide the user with good health; that the article was effective for sores on the face and body; that its calcium chloride content would enable it to produce red blood, and that its magnesium

content would act as a cleansing agent; that many major diseases are caused by deposits of inorganic minerals in the body (joints, blood vessels, etc.), and that the article would put such minerals to work for health; that the article would prevent stiffening and excess depositing of minerals in the tissues, thus preventing or relieving arthritis, high blood pressure, or other ailments; that it would render water-soluble deposited or crystallized minerals and metals in and on the tissues, making these more flexible; that it would cause the body to assimilate minerals deposited in or on the tissues; that it would dissolve and remove tissue waste, the principle cause of sickness, and thus benefit the sick; that it would prevent trace elements ingested in larger quantities than the body can use from causing poor health as a result of metal or mineral poisoning; that it was a wonderful aid to arthritic patients by reason of its ability to break down excessive calcium deposits in the joints; that it would move poisons in the body; that it would remove cholesterol, the cause of high blood pressure, gallstones, and scores of other ailments, keeping it in solution; that it would restore health and provide the necessary elements for the structure and vitality of the organs; that every disease is due to a lack of one or more inorganic salts, and that health and strength could be maintained by supplying these salts through the medium of the article; that the article was capable of healing all diseases which are curable to all; that it would be effective in curing long-standing chronic diseases brought on by over-dosing, excessive use of quinine, mercury, etc.; that it would remedy the chronic forms of nervous debility, rheumatism, asthma, anemia, diabetes, goiter, organic heart disease, neuralgia, paralysis, varicose veins, catarrh, and dropsy; that by reason of its content of sulfate of calcium, the article would act as a preventive of cell disintegration and suppuration and would be effective in the third state of all suppurative processes, including catarrhs, lung troubles, boils, carbuncles, ulcers, abscesses, pimples and pustules of the face, and all cases of true suppuration; that by reason of its chloride of potash content, it was indicated in glandular swelling, discharges or expectoration of a thick, white, fibrous consistency, white or gray exudations, and was excellent in catarrhal conditions with those symptoms; that it was effective in croup, diphtheria, dysentery, and pneumonia, and in the control of plastic exudation; that by reason of its chloride of soda content, it would act on the blood, liver, spleen, and every mucous membrane of the body; that it was indicated in headache, toothache, face-ache, stomachache, vomiting of water and mucus, catarrhal affections of mucous membranes, with secretion of transparent, frothy, watery mucus, small, watery blisters or blebs on the skin, diarrhea, slimy, transparent stools, inflammation of the eyes, leucorrhea, and for washing drugs from the system; that by reason of its silica content, the article would ripen abscesses and would promote suppuration; that it would cure chronic, gouty rheumatic affections and restore suppressed foot-sweats, thus indirectly remedying diseases resulting from suppression of foot-sweat, such as amblyopia, cataract, paralysis, etc.; that it would prevent atrophy; that it would favorably affect the central and peripheral nervous systems, as in languor, sleepiness, anxious dreams, nervous irritability, depression, headaches, trembling, and paretic symptoms; that by reason of its chlorine content, the article would aid in the regulation and stimulation of muscular action; that by reason of its magnesium content, it would favorably affect muscular activity, nerve stability, and bone structure, and would have a laxative effect; that by reason of its sodium content, it would maintain normal heart action; that it would prevent rapid disintegration of cell tissues; that by reason of its radium content, it would have a beneficial effect; that it

would render one free from all symptoms of rheumatism; that it was a remedy for diabetes mellitus, holding out a reasonable hope that where the pancreatic gland is not too much destroyed, it would restore the gland to its normal function; that there was reason to believe that it would be decidedly helpful in tuberculosis; that it would cure high blood pressure and produce excellent results in severe cases of laryngitis accompanied by an ulcerated mouth; that it would remedy unbearable pain in the legs and cure pyorrhea; that if used as a rinse for the mouths of children, it would decrease their aches and pains and ill health caused by pyorrhea; that it would relieve external itching of seven years' duration; that it would give quick recovery from an alcoholic "binge"; that is would cut short the common cold, la grippe, and bronchitis; that it would produce a healthy pink color in the face; that it would cause response from disease conditions in cases of all sorts where no response had resulted from the usual medical and hospital treatment, various diets, and/or drugless treatment; that the article would cause remarkable recovery from hives of long standing, high blood pressure, diabetes, ulcers of the stomach, arthritis, leg pains, kidney and bladder trouble, loss of appetite, etc.; that it was more effective in getting the average patient back towards, health than the vitamins; that it was beneficial when applied externally for ulcers; that it would supply salts not obtainable in food because of depleted soils and cooking; that it would cure duodenal and pyloric ulcers, kidney and bladder troubles, diabetes, arthritis, and rheumatism; that it would enable the diabetic to abandon the use of insulin; that it would relieve gastric ulcers and render the sufferer stronger and more buoyant; that it would supply energy and pep; that it would make one feel like one of half his age; that it would remedy a weakened condition and dizzy spells and enable one to sleep; that it would correct nervous stomach and shorten the course of the grippe and the "grippy" cold and "achy" feelings accompanying that condition; and that it would prevent the loss of sense of smell and taste during a cold.

DISPOSITION: September 27, 1950. R. & S. Nutrients, Inc., Washington, D. C., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the booklets be destroyed and that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The booklets were destroyed, and the bottles were relabeled.

3299. Misbranding of Weber's liniment. U. S. v. 105 Bottles, etc. (F. D. C. No. 29741. Sample No. 13747-K.)

LIBEL FILED: September 20, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 24, 1950, from Baltimore, Md.

PRODUCT: Weber's liniment. 105 8-ounce bottles, 24 ½-gallon jugs, and 1 1-gallon jug at Chambersburg, Pa., in possession of the consignee, H. Weber & Co.

RESULTS OF INVESTIGATION: The product was shipped in 5-gallon bottles. After completion of the interstate shipment, the product was repackaged and labeled by the consignee. At the time of the investigation, the consignee had in his possession a number of leaflets entitled "Weber's Liniment," which were distributed by the salesman for the consignee at the time sales of the product were made.

Analysis showed that the product consisted essentially of alcohol, 77 percent, ammonia, camphor, sassafras oil, cayenne pepper, and water.

LABEL, IN PART: "The Genuine Weber's Liniment * * * Alcohol 81%."

Nature of Charge: Misbranding, Section 502 (a), certain statements on the label of the article and in the accompanying leaflets were false and misleading since they represented and suggested that the article was an adequate and effective treatment for sprains and bruises, swollen, stiff joints of wrists and ankles, neuralgia, rheumatic pains, lumbago, neuralgia of face, sore throat, colds and coughs, croup, wounds, frosted feet, poison ivy, sunburn, skin irritations, burns, scalds, cramps, and indigestion of humans, and for gapes, roup, colds, diarrhea, coccidiosis, cholera, worms, and allied ailments of poultry; that it would be effective to promote healthy, vigorous growth of poultry; and that it would be an adequate and effective treatment for scours in calves and colts and for distemper in horses and cattle, whereas the article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 24, 1950. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE*

3300. Misbranding of Solution 5-17, Tur-Abken, Hex-Emia, Avian iodine, solution sulfathiazole sodium, solution sulfamethazine sodium, Solution Sulfathia-Zine, Anti-Pick, and sulfathiazole ointment. U. S. v. 52 Bottles, etc. (F. D. C. No. 29378. Sample Nos. 75211-K, 75212-K, 75215-K to 75219-K, incl., 75221-K, 75222-K.)

LIBEL FILED: July 6, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about March 21, 1950, by the Southwest Laboratories, from San Diego, Calif.

Product: 62 bottles of Solution 5-17, 62 bottles of Tur-Abken, 4 bottles of Hex-Emia, 4 bottles of Avian iodine, 11 bottles of solution sulfathiazole sodium, 10 bottles of solution sulfamethazine sodium, 10 bottles of Solution Sulfathia-Zine, 2 jars of Anti-Pick, and 4 jars of sulfathiazole ointment at Denver, Colo., together with a number of pamphlets entitled "Seal of Quality Remedies" and "Seal Brand Remedies Control Coccidiosis Enteritis Bronchitis And Colds."

Analysis disclosed that the Solution 5-17 consisted essentially of lactic, tartaric, citric, and acetic acids, and phenolphthalein (0.3 percent), dissolved in water; that the Anti-Pick consisted essentially of an ointment containing guaiacol and colocynth extract in a base of petrolatum and paraffin, colored red; and that the sulfathiazole ointment consisted essentially of sulfathiazole, 2 percent, in an ointment base, perfumed with menthol. The remaining products were not analyzed, but apparently their composition conformed with that disclosed on the labels, which represented that the Tur-Abken contained eucalyptus oil, guaiacol, white pine oil, bland oil, and chlorophyll; that the Hex-Emia consisted of a liquid concentrate of pure lactic acid, iron chloride, and copper sulfate; that the Avian iodine was a mixture of iodine and iodide; that the solution sulfathiazole sodium contained 30 grains of sulfathiazole sodium sesquihydrate in each ounce; that the solution sulfamethazine sodium contained 171/2 grains of sodium sulfamethazine per fluid ounce; that the Solution Sulfathia-Zine contained 17 grains of sodium sulfathiazole and 10 grains of sodium sulfamethazine per fluid ounce. The bottles and jars containing the product ranged in size from 2 ounces to 1 gallon.

^{*}See also No. 3299.

LABEL, IN PART: "Solution 5-17," "Tur-Abken," "Seal Brand Hex-Emia (Solution)," "Seal Brand Avian Iodine (Liquid)," "Seal Brand Solution Sulfathiazole Sodium [or "Sulfamethazine Sodium" or "Sulfathia-Zine"]," and "Seal Brand Anti-Pick [or "Sulfathiazole Ointment"]."

NATURE of CHARGE: Solution 5-17. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since such statements represented and suggested that the article was effective for the prevention and treatment of coccidiosis, enteritis, other intestinal diseases in chickens, rabbits, and turkeys, and intestinal diseases and parasites of poultry and diarrhea of rabbits; and that the article would change the intestinal condition from an acid to an alkaline balance and so maintain a normal appetite, whereas the article was not effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the name of the active ingredient, phenolphthalein, contained therein.

Tur-Abken. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since such statements represented and suggested that the article was effective for the prevention and treatment of colds and swell heads in turkeys, rabbits, and chickens, bronchitis in chickens, sprains, and lameness, whereas the article was not effective for such purposes.

Hex-Emia: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective for the prevention and treatment of hexamitiasis, mycosis, enteritis, and anemia in poultry, and that it would lessen the percentage of mortality, whereas the article was not effective for such purposes.

Avian iodine. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective for the prevention and treatment of enlarged livers, anemia, faulty blood conditions, weakened kidneys, blackhead, leukosis, and ailments of the liver and kidneys in poultry; that it would build disease resistance; and that such conditions are caused by an iodine deficiency in water and feed. The article was not effective for such purposes, and the conditions named are not caused by an iodine deficiency in water and feed.

Solution sulfathiazole sodium. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for coryza (colds) in poultry and colds in rabbits. The article was not an effective treatment for coryza (colds) in poultry or colds in rabbits when used as directed in its labeling, namely: "Add Two (2) Tablespoons (one ounce) of Seal Brand Solution Sulfathiazole in each gallon of drinking water for Five (5) Days. Sixth day replace with two (2) tablespoons of Soda or Epsom Salts. (One Day Only.) Ninth day repeat Solution Sulfathiazole dosage. Tenth day repeat Soda or Salts. (One Day Only.)"

Solution sulfamethazine sodium. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for coccidiosis, pullorum disease, and fowl cholera in poultry. The article was not effective in the treatment of coccidiosis, pullorum disease, and fowl cholera in poultry when used as directed in its labeling, namely: "Add Four (4) Tablespoons (2 ounces) Seal Brand Solution—Sulfamethazine in each gallon

of drinking water for Two Full Days. Give plain drinking water for the next four days. Then on the seventh day of the dosage period Repeat Seal Brand Solution—Sulfamethazine for One Day Only."

Solution Sulfathia-Zine. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for colds and coryza, pullorum disease, coccidiosis, and fowl cholera in poultry and rabbits. The article was not effective in the treatment of such disease conditions when used as directed in its labeling, namely: "Add Three (3) Tablespoons (1½ ounces) of Seal Brand Solution Sulfathia-Zine to each gallon of drinking water for Three (3) Days. Sixth day replace with Two (2) tablespoons of Soda or Epsom Salts. (One Day Only.) Ninth day repeat Solution Sulfathia-Zine dosage. Tenth day repeat Soda or Salts. (One Day Only.)"

Anti-Pick. Misbranding, Section 502 (a), the label of the article bore statements which represented and suggested that the article had healing properties when applied to fowls which had been picked by other fowls, whereas such statements were false and misleading since the article was not effective for such purpose; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient contained therein since its label bore no ingredient statement.

Sulfathiazole ointment. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was healing; that it was an effective treatment for bruises and caked udders; and that it would aid in healing all cuts, burns, and swellings. The article was not healing; it was not an effective treatment for bruises and the several disease conditions of the mammary gland known as caked udders; and it would not aid in the healing of all cuts, burns, and swellings.

DISPOSITION: August 25, 1950. The shipper of the articles having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the court ordered that the products, including the pamphlets, be destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3281 TO 3300 PRODUCTS

N. J. No.	N. J. No.
Amphetamine sulfate, dl 3293	Iodine, Avian 3300
Anti-Pick 3300	Laxative without required warn-
Asthma, remedy for 13297	ing statements 3289
Avian iodine 3300	Liniment, Weber's 3299
Bactra-Tycin ointment 3295	Magnesia tablets, milk of 3294
Benzedrine Sulfate tablets 3282, 3283,	
3285	Milk of magnesia tablets 3294
	Mineral water 3298
	Morse's, Dr., Indian Root pills 3289
Comstock's Dead Shot worm	Nembutal-C tablets 3285
pellets 3289	Sodium capsules 3285, 3286
Cosmetic (subject to the drug	Ointment 3295, 3300
provisions of the Act):	Parenteral drug, contaminated 3291
Dr. Shokunbi's F-62 Herbal	
Hair Growing Aid 13297	Phenobarbital tablets 3287
Dead Shot worm pellets, Com-	Seconal Sodium capsules 3283, 3284
stock's 3289	Shokunbi's, Dr., F-219 Asthma
Devices 3296	Aid, Dr. Shokunbi's Tree of
Dexedrine Sulfate tablets 3281, 3282,	Life F-218, Dr. Shokunbi's
3285	F-62 Herbal Hair Growing
Dextro-amphetamine phosphate	Aid, and Dr. Shokunbi's
	F-214 Nervine 13297
and dextro-amphetamine sul-	Sulfadiazine tablets 3281, 3282
fate3292	Sulfamethazine sodium, solution 3300
Diethylstilbestrol tablets 3281, 3282	
Dl-amphetamine sulfate 3293	Sulfathia-Zine, Solution 3300
Estrogenic substance 3291	Sulfathiazole ointment and solu-
5–17, Solution 3300	tion sulfathiazole sodium 3300
Geo-Mineral 3290	Thermometers, clinical 3296
Gothestrone 3291	Thyroid tablets 3282
Hair and scalp preparation 13297	Tur-Abken 3300
Hex-Emia 3300	Veterinary preparations 3299, 3300
Indian Root pills, Dr. Morse's 3289	Water, mineral 3298
Injection preparations. See Par-	Weber's liniment 3299
enteral drug, contaminated.	Worms, remedy for 3289
	1,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
SHIPPERS MANUFACTION	RERS, AND DISTRIBUTORS
DAIL LIES, MARGINGIO	ALICO, AND DISTRIBUTORS
N. J. No.	N. J. No.
African Herb & Chemical Co.	Comstock, W. H., Co., Ltd.:
See Shokunbi, S. P.	Dr. Morse's Indian Root pills
Amick, H. N.:	and Comstock's Dead Shot
Nembutal-C tablets, Nembutal	worm pellets 3289
Sodium capsules, Benzedrine	Consolidated Thermometer Co.:
Sulfate tablets, and Dexe-	
drine Sulfate tablets 3285	clinical thermometers 3296
City Drug Co. See McDaniel,	Downs, L. E.:
С. Н.	cancer cure 3288

^{1 (3297)} Prosecution contested.

N. J.	No. 1 No. 1
Geo-Mineral Co.:	Shokunbi, S. P.—Continued
Geo-Mineral 32	90 Aid, and Dr. Shokunbi's
Gotham Pharmaceutical Co.,	F-214 Nervine 1 3297
Inc.:	Smith, B. T.:
Gothestrone 32	91 Nembutal Sodium capsules 3286
Grossman, Max:	Smith, B. T., Co., Inc.:
Gothestrone32	91 Nembutal Sodium capsules 3286
Hergenrather, Louis, 3d:	Southwest Laboratories:
	Solution 5-17, Tur-Abken, Hex-
Hoxsey Cancer Clinic:	Emia, Avian iodine, solution
	sulfathiazole sodium, solu-
Kolb, F. J., Jr.:	tion sulfamethazine sodium,
diethylstilbestrol tablets, Dex-	Solution Sulfathia-Zine, Anti-
edrine Sulfate tablets, Ben-	Pick, and sulfathiazole oint-
zedrine Sulfate tablets, sul-	ment 3300
fadiazine tablets, and thyroid	Spigelmire, C. E.:
	Nembutal Sodium capsules 3286
McDaniel, C. H.:	Tru-Synthetics, Inc.:
diethylstilbestrol tablets, sul-	dextro-amphetamine phosphate
fadiazine tablets, and Dexe-	and dextro-amphetamine sul-
***	81 fate
Matthias, W. C.:	dl-amphetamine sulfate 3293
	Turnbow, T. P.:
Matthias Prescription Pharmacy,	diethylstilbestrol tablets, Dexe-
Inc.:	drine Sulfate tablets, Ben- zedrine Sulfate tablets, sul-
Pay Less Drug Store: Geo-Mineral 32	fadiazine tablets, and thyroid tablets3282
Piotrowski, S. E.:	Vi-Jon Laboratories, Inc.:
	Geo-Mineral 3290
Seconal Sodium capsules and Benzedrine Sulfate tablets 32	83 Wallace Laboratories, Inc.:
	Bactra-Tycin ointment 3295
Piotrowski, Stephen E., Phar-	Weber, H., & Co.:
macy. See Piotrowski, S. E. Pitman-Wilson Co.:	Weber's liniment 3299
	Wiegand, E. E.:
Nembutal-C tablets, Nembutal	Seconal Sodium capsules 3284
Sodium capsules, Benzedrine	Wilson, A. G.:
Sulfate tablets, and Dexedrine Sulfate tablets 32	diethylstilbestrol tablets, Dexe-
R. & S. Nutrients, Inc.:	drine Sulfate tablets, Benze-
	98 drine Sulfate tablets, sulfa-
Rey Mfg. Co.:	diazine tablets, and thyroid
	94 tablets 3282
Rogers, J. L.:	Wilson & Little Pharmacy:
9	98 diethylstilbestrol tablets, Dexe-
Shokunbi, S. P.:	drine Sulfate tablets, Benze-
Dr. Shokunbi's F-219 Asthma	drine Sulfate tablets, sulfa-
Aid, Dr. Shokunbi's Tree of	diazine tablets, and thyroid
Life F-218, Dr. Shokunbi's	tablets 3282
	0202

^{1 (3297)} Prosecution contested.



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law.

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Sciurities
Shipping
Social Security
Taxation
Utilities
Veterany Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3301-3320

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs.

WASHINGTON, D. C., April 4, 1951.

CONTENTS*

Page	Page
Drugs and devices actionable be-	Drugs and devices actionable be-
cause of failure to bear ade-	cause of false and misleading
quate directions or warning	claims 292
statements 276	Drugs for human use 292
Drugs and devices actionable be-	Drugs for veterinary use 296
cause of deviation from official	Index
or own standards 291	

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3301-3308: omission of, or unsatisfactory, ingredients statements, Nos. 3302, 3303, 3305; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3301-3308, 3313; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3302-3305, 3307, 3308, 3313, 3316; cosmetics actionable under the drug provisions of the Act, No. 3316 (DermaCulture Formula No. 103, cleansing lotion herbal astringent, granular cleanser, DermaCulture Formula No. 102, and DermaCulture Formula No. 104)

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3301. Misbranding of Seconal Sodium capsules. U. S. v. Jones Drug Co. and Walter W. Hafley. Pleas of guilty. Fine of \$20 against each defendant. (F. D. C. No. 29478. Sample Nos. 31933-K, 31935-K, 58077-K, 58152-K.)
- INFORMATION FILED: November 1, 1950, District of Arizona, against the Jones Drug Co., a partnership, Tucson, Ariz., and Walter W. Hafley, a partner in the partnership.
- INTERSTATE SHIPMENT: Between the approximate dates of April 14 and June 15, 1949, from the State of Indiana into the State of Arizona.
- ALLEGED VIOLATION: On or about July 20 and August 12, 23, and 25, 1949, while the drug was held for sale after shipment in interstate commerce, the defendant caused a number of the *Seconal Sodium capsules* to be repacked and sold without a prescription, which acts resulted in the capsules being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents. Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the directions for use "One capsule at bedtime," borne on the labeling of the repackaged capsules, were not adequate directions for use.

- DISPOSITION: November 15, 1950. Pleas of guilty having been entered, the court imposed a fine of \$20 against each defendant.
- 3302. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets.
 U. S. v. Joseph P. Piszczek (Piszczek's Pharmacy). Plea of guilty. Fine
 \$300. (F. D. C. No. 29445. Sample Nos. 15846-K to 15849-K, incl.)
- Information Filed: September 6, 1950, Eastern District of Wisconsin, against Joseph P. Piszczek, trading as Piszczek's Pharmacy, Milwaukee, Wis.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of Seconal Sodium capsules and Benzedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about October 7, 10, 13, and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the Seconal Sodium capsules and the Benzedrine Sulfate tablets to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use; and Section 502 (b) (1), a portion of the repackaged Seconal Sodium capsules failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations

designated as, habit forming; and when repackaged, the label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: November 27, 1950. A plea of guilty having been entered, the court imposed a fine of \$300.

- 3303. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Budner's Pharmacy, Morris Ridberg, and William C. Durr. Pleas of guilty. Fine of \$250 against pharmacy and \$150 against each individual. (F. D. C. No. 29446. Sample Nos. 15858-K to 15856-K, incl.)
- Information Filed: September 11, 1950, Eastern District of Wisconsin, against Budner's Pharmacy, a partnership, Milwaukee, Wis., and Morris Ridberg, a partner in the partnership, and William C. Durr, a pharmacist for the partnership.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of Seconal Sodium capsules and Benzedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about October 10, 13, and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.
- NATURE of CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

- DISPOSITION: November 27, 1950. Pleas of guilty having been entered, the court imposed a fine of \$250 against the partnership and a fine of \$150 against each individual.
- 3304. Misbranding of Seconal Sodium capsules, Dexedrine Sulfate tablets, and Nembutal Sodium capsules. U. S. v. Robert J. Evans and Charles C. Drummond (Evans-Drummond Drug Store). Pleas of nolo contendere. Fine of \$50 against each defendant. (F. D. C. No. 28142. Sample Nos. 53861-K, 53862-K, 53875-K, 53876-K, 54128-K, 54133-K, 54137-K, 54138-K, 54140-K, 54221-K.)
- Information Filed: September 14, 1950, Southern District of Mississippi, against Robert J. Evans and Charles C. Drummond, copartners, trading as the Evans-Drummond Drug Store, Hattiesburg, Miss.

INTERSTATE SHIPMENT: From the State of Louisiana into the State of Mississippi, of quantities of Seconal Sodium capsules, Dexedrine Sulfate tablets, and Nembutal Sodium capsules.

ALLEGED VIOLATION: On or about July 28 and August 9, 12, and 15, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions "One when necessary," "Take one when needed," and "One with water, repeat 4 to 6 hours as needed for nervousness" borne on the labeling of portions of the repackaged drugs were not adequate directions for use, and since the labeling on other portions of the repackaged drugs bore no directions for use; and, Section 502 (b) (1), portions of the repackaged Dexedrine Sulfate tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the Seconal Sodium capsules and the Nembutal Sodium capsules contained derivatives of barbituric acid, which derivatives, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: October 10, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$50 against each defendant.

3305. Misbranding of pentobarbital sodium capsules, Seconal Sodium capsules, amphetamine phosphate tablets, and sulfadiazine tablets. U. S. v. Excel Drugs, Jack Cowan, and Ferd B. Heinzle. Pleas of guilty. Fine of \$900 against Excel Drugs, \$250 against Jack Cowan, and \$200 against Ferd B. Heinzle. (F. D. C. No. 29462. Sample Nos. 55381-K, 55385-K to 55387-K, incl., 55389-K, 55392-K to 55394-K, incl., 55397-K.)

INFORMATION FILED: October 10, 1950, Western District of Missouri, against Excel Drugs, a partnership, Kansas City, Mo., and Jack Cowan and Ferd B. Heinzle, pharmacist and employee, respectively, for the partnership.

INTERSTATE SHIPMENT: From the States of New Jersey, Indiana, New York, and Pennsylvania into the State of Missouri, of quantities of pentobarbital sodium capsules, Seconal Sodium capsules, amphetamine phosphate tablets, and sulfadiazine tablets.

ALLEGED VIOLATION: On or about December 19, 22, and 23, 1949, while the drugs were being held for sale at Excel Drugs after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded. Excel Drugs, Jack Cowan, and Ferd B. Heinzle, in 9 counts, 5 counts, and 4 counts, respectively, were charged with causing the acts of repacking and sale of the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 52 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules and the Seconal Sodium capsules contained derivatives of barbituric acid, which derivatives, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the capsules failed to bear labels containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged amphetamine phosphate tablets and the sulfadiazine tablets failed to bear labels containing the common or usual name of the drugs; and, Section 502 (f) (2), the repackaged amphetamine phosphate tablets and the sulfadiazine tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: November 10, 1950. Pleas of guilty having been entered, the court imposed a fine of \$900 against the partnership, \$250 against Jack Cowan, and \$200 against Ferd B. Heinzle.

3306. Misbranding of pentobarbital sodium capsules. U. S. v. James W. Moore (Lenhart Drug Store). Plea of nolo contendere. Fine of \$175, plus costs. (F. D. C. No. 29441. Sample Nos. 41076-K, 41080-K, 41081-K, 64084-K, 64093-K, 64701-K, 64709-K.)

Information Filed: November 2, 1950, District of North Dakota, against James W. Moore, trading as the Lenhart Drug Store, Bismarck, N. Dak.

ALLEGED SHIPMENT: On or about June 1, 13, and 24, October 17, November 4 and 22, and December 6, 1949, from the State of North Dakota into the States of Montana and Minnesota.

NATURE of CHARGE: Misbranding, Section 502 (b) (2), the article failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use "One capsule at bedtime when needed" and "Swallow one every four hours for restlessness and then as directed," borne on the labeling of the article, were not adequate directions for use.

Disposition: November 9, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$175, plus costs.

- 3307. Misbranding of Seconal Sodium capsules, dextro-amphetamine hydrochloride tablets, phenobarbital tablets, and sulfadiazine tablets. U. S. v. George E. Stone (Stone's Drug Store). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 29429. Sample Nos. 27078-K, 61046-K, 61426-K, 61738-K.)
- Information Filed: June 28, 1950, Western District of Kentucky, against George E. Stone, trading as Stone's Drug Store, Mayfield, Ky.
- Interstate Shipment: From the States of Indiana, Pennsylvania, and Missouri into the State of Kentucky, of quantities of Seconal Sodium capsules, dextroamphetamine hydrochloride tablets, phenobarbital tablets, and sulfadiazine tablets.
- ALLEGED VIOLATION: On or about September 27, 28, and 29, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *sulfadia- zine tablets* failed to bear a label containing the name and place of business of
 the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the
 repackaged drugs failed to bear labels containing statements of the quantity
 of the contents.

Further misbranding, Section 502 (d), the Seconal Sodium capsules and the phenobarbital tablets contained chemical derivatives of barbituric acid, which derivatives, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the capsules and tablets failed to bear labels containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of all of the repackaged drugs bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged dextro-amphetamine hydrochloride tablets and the sulfadiazine tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: October 23, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$200.
- 3308. Misbranding of diethylstilbestrol tablets and phenobarbital tablets. U. S. v. Ernest Smith. Plea of nolo contendere. Fine, \$100. (F. D. C. No. 29418. Sample Nos. 27069-K, 27070-K.)
- Information Filed: June 7, 1950, Western District of Kentucky, against Ernest Smith, manager of the Owl Drug Co., Fulton, Ky.
- INTERSTATE SHIPMENT: From the States of Indiana and Texas into the State of Kentucky, of quantities of diethylstilbestrol tablets and phenobarbital tablets.
- ALLEGED VIOLATION: On or about September 28, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the

manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the tablets failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: October 23, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100.

3309. Action to enjoin and restrain the interstate shipment of a drug known as Nurse Dencker's ointment. U. S. v. Mimi E. Alcorn, William Vernon Alcorn, and Wilhelmina G. Stanley (Dencker Products). Consent decree granting injunction. (Injunction No. 135.)

COMPLAINT FILED: September 8, 1947, Southern District of California, against Mimi E. Alcorn, William Vernon Alcorn, and Wilhelmina G. Stanley, trading as Dencker Products, Long Beach, Calif.

NATURE OF CHARGE: That the defendants had been and were at the time of filing the complaint, introducing and delivering for introduction into interstate commerce quantities of the drug known as *Nurse Dencker's ointment*, consisting of zinc oxide, corn starch, salicylic acid, olive oil, vaseline, and 1 percent of carbolic acid.

The drug was alleged to be misbranded under Section 502 (a), in that certain statements in the accompanying labeling of the drug were false and misleading. The statements represented, suggested, and implied that the drug would be efficacious in the cure, mitigation, and treatment of surface skin irritations, such as leg sores, superficial sores, lesions, and irritations on the legs, arms, body, whereas the drug was not efficacious for such purposes.

The drug was alleged also be misbranded under Section 502 (f) (1), in that the directions for use, "Clean parts with pure olive oil, wipe dry, then apply ointment thickly, fresh every morning and night—bandage," appearing on the label, were inadequate for the use of the drug in the various disease conditions for which it was prescribed, recommended, and suggested in the labeling and advertising disseminated by the defendants.

The complaint alleged also that unless restrained, the defendants would continue to introduce and deliver for introduction into interstate commerce the misbranded drug.

Disposition: October 30, 1950. The defendants having consented to the entry of a decree, the court issued an order permanently enjoining the defendants from directly or indirectly introducing or delivering for introduction into interstate commerce the drug in question, or any like drug, misbranded as alleged in the complaint.

3310. Misbranding of Ri-Co tablets. U. S. v. 33 Bottles * * *. Claimant's exceptions to the libel overruled. Government's motion for summary judgment granted. Decree of condemnation and destruction. Judgment affirmed upon appeal. (F. D. C. No. 22157. Sample No. 48752-H.)

LIBEL FILED: January 8, 1947, District of Colorado.

ALLEGED SHIPMENT: On or about November 25, 1946, by the Alberty Food Products Co., from Hollywood, Calif.

PRODUCT: 33 bottles each containing 275 Ri-Co tablets at Denver, Colo.

Label, in Part: "Ri-Co Tablets. Homeopathic Combination."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the only direction appearing in the labeling, namely, "Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.," did not indicate the purpose or condition for which the article was intended and, therefore, was not adequate for intelligent and effective use.

DISPOSITION: On February 28, 1947, pursuant to agreement between the Alberty Food Products Co. and the Government, the libel proceedings were ordered transferred to the United States District Court for the Northern District of California. Thereafter, exceptions to the libel were taken by the claimant, Alberty Food Products Co., and on September 30, 1947, the court overruled the exceptions. On December 1, 1947, the claimant filed an answer denying that the product was misbranded as alleged in the libel. On October 15, 1948, the Government filed a motion for summary judgment, and after a hearing in the matter, the court, on November 16, 1949, rendered the following oral opinion:

Black, District Judge:

The CLERK. "United States v. 33 Bottles of Ri-Co Tablets. Motion for Summary Judgment, for decision.'

Mr. Hauerken. "Ready." Mr. Dickerman. "Your Honor, may I request I be heard briefly on a new development that came to my attention this morning. It involves another case, or another libel with the Food and Drug Law wherein the District Court of the Northern District of Illinois granted motion for summary judgment. I have a mimeographed copy of this opinion which I received this morning. I gave a copy to counsel."

The COURT. "You may hand it to me."

Mr. DICKERMAN. "I wish to call the attention of the Court, the question apparently was not raised as to whether the admiralty or civil rules applied." The COURT. "In the matter of the United States of America v. 33 Bottles,

More or Less, of an Article Labeled in Part 'Ri-Co Tablets Homeopathic Combination App. 275 Tablets,' Alberty Food Products Co., etc., Claimant, the Government is asking for summary judgment. The claimant suggested in the first instance that summary judgment is not applicable on the ground that under the statutes the proceeding is to be considered as one in admiralty, and that therefore the civil rules of Federal Procedure providing for summary judgment do not authorize action by the Court as requested by the Government.

"I say that the claimant has suggested that summary judgment is not applicable. Actually, counsel for claimant has further suggested to the Court that condemnation is appropriate and should be ordered, but that the Court should further provide that the claimant should be permitted to relabel the bottles in accordance with the practice counsel says the claimant is now following pursuant to a decision by the Federal Trade Commission. In effect, then, I take it the question of whether or not this is a proceeding in admiralty is, in so far as counsel is able to make it, somewhat academic. It might almost be said that it is the law of this particular case that condemnation on the record should enter, and that the issue is whether or not relabeling should be permitted.

"I have looked at the authorities: the decision of the Supreme Court in 226 U. S., beginning at page 172; 33 Supreme Court, beginning at page 50; and 57 Law Edition, page 175, has been cited to the Court by the Government as establishing that this proceeding is civil and is not one in admiralty. That Supreme Court decision in substance held that the law then before the Supreme Court likened the proceedings to one [in] admiralty in connection with the seizure of the property by process in rem, and that decision of the United States Supreme Court in effect was that after the seizure the matter became a proceeding in law and was governed by the statutes and rules apart from

admiralty.

"Counsel for the plaintiff has pointed out that that decision was before the enactment of the present statute. After reading the Supreme Court decision, it seems to me that the principal therein enunciated, properly applied to the present statute, strongly indicates that it is to be deemed a civil rather than an admiralty matter after the seizure. It would therefore appear that summary judgment would be applicable.

"My view of the force and effect of that Supreme Court decision, which I think was about 1912, is in harmony with the view of the Circuit Court of Appeals for the Sixth Circuit, after the enactment of the present statute, which decision was rendered June 22, 1943, and is found in 136 Fed. Rep., 2nd Series, beginning at page 523. The Court of Appeals of the Sixth Circuit, in substance, held that the proceeding was not intended to be likened to one in admiralty beyond the seizure of the property by process in rem under the

statutes.

Under the decisions cited to me, I am satisfied that the Federal Rules of Civil Procedure are effective and that a summary judgment, upon proper

showing, can be entered.

"There has just been handed to me District Court decision from the Northern District of Illinois, United States v. 17 Cases, More or Less, of Nue-Ovo, Research Laboratories, Inc. In this decision, dated October 11, 1949, the judge assumed that entry of a summary judgment was within his authority. It does not appear, however, that anyone objected to his exercising the authority providing the showing was sufficient. But independently of this most recent decision, I am satisfied that the proceeding is, at this stage, not one in admiralty. The main contention of the claimant is that by virtue of the Federal Trade decision, the holding that its right to relabel these articles is established be on the doctrine of res adjudicata. Such is a most interesting contention. Counsel for claimant depends primarily upon the decision of the United States v. Willard Tablet Company, 141 Fed. (2d), beginning at page 141, being a decision by the Circuit Court of Appeals of the Seventh Circuit under date of March 7, 1944. That court undoubtedly does hold that a decision by the Federal Trade Commission is binding upon the court in an independent proceeding; and the court in that decision depended upon an earlier decision by the Circuit Court of Appeals for the Eighth Circuit in Lee v. Federal Trade Commission, 113 Fed. (2d) 583. However, the Circuit Court of Appeals for the Ninth Circuit, under date of February 24, 1942, in U. S. v. Research Laboratories, Inc., reversing a holding by myself at Tacoma, said the following:

It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled "What is Arthritis?" The power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order, or either by the fact, if it be a fact, that such an order has actually issued.

"I am bound and controlled by the decision of this circuit, regardless of whether I agree or disagree with its correctness. I am only to be persuaded by the decisions of the Seventh Circuit or the Eighth Circuit if they appeal to my reason and are not at variance with the decisions of the Court of Appeals for the Ninth Circuit.

"December 8, 1943, 139 Fed. Rep. (2d), page 197, in the Sekov Corporation v. United States, the Circuit Court of Appeals for the Fifth Circuit cited with approval the decision of 122 Fed. (2d) 42, U.S. v. Research Laboratories, of this Ninth Circuit, which I have just mentioned."
Mr. HAUERKEN. "Your Honor, may I say a word?"
The COURT. "It stated this:

Appellant Sekov Corporation contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government's libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District Court to condemn the misbranded articles

was not impaired or diminished by the former proceeding. United States v. Research Laboratories, 9 CIR., 126 Fed. (2d) 42, 45.

"While the decision of the Eighth Circuit in 113 Fed. (2d) 583, which I previously mentioned, appealed to the Court of Appeals for the Seventh Circuit in the Willard Tablet Company case, such decision in 113 Fed. (2d) neither appealed to the Circuit Court of Appeals for the Fifth Circuit nor

to the Circuit Court of Appeals for the Ninth Circuit.

"Unquestionably I must hold that what the Federal Trade Commission did in an independent and different proceeding is not res adjudicata here. Actually, such would appear not to be res adjudicata for further reasons. In the first place, what the Trade Commission did apparently was done pursuant to stipulation. Other courts, in independent proceedings where the showing is different, are very reluctant to consider themselves barred by a commission's holding on a stipulation. Further than that, I do not find that the Commission held anything. I am advised that the cease and desist order of the Federal Trade Commission required this claimant to cease and desist from disseminating advertisements in the United States mails or by any means in commerce which represent

that the preparation "Ri-Co Tablets" constitutes an adequate or competent treatment for arthritis, rheumatism, gout or rheumatic gout; or that said preparation will eliminate uric acid from the system; provided, however, that nothing herein shall be construed as prohibiting the representation that according to the principles of the homeopathic school of medicine the preparation is of value in ameliorating the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism except when such symptoms are accompanied by a febrile condition.

"It is apparent that the Federal Trade Commission did not hold that Ri-Co Tablets were of value to ameliorate the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism. The most that the Federal Trade Commission said was that it was not preventing the claimant from contending that such was of benefit. That is a far cry from any adjudication that should be considered as res adjudicata.

"But even if the Federal Trade Commission had done what counsel feels it did do, the Circuit Court of Appeals for the Ninth Circuit certainly told me that any holding of any Federal Trade Commission was of no avail in another and independent proceeding before the District Court. There is no showing in behalf of the claimant before me that the tablets have any efficiency or any value. All of the showing, so far as presented, is to the effect that they are worthless.

"The application for summary judgment based upon the pleadings, however, is upon the ground that the labels did not give adequate directions as required by the statute. The label did state that the tablets were to be taken at certain intervals, without even a hint that the tablets were helpful for anything. The Government's contention is that the directions, to be adequate, must not only tell how often the alleged remedy is to be taken, but for what it is to be used. The decisions of the Circuit Court of Appeals in this Circuit, both of the District Courts and of the Court of Appeals, are to the effect that as to remedies' directions, to be adequate they must not only say how often but for what.

"It seems to me that such holdings which are binding upon me are in accord with reason and in harmony with the purpose of the Pure Food and Drug Act.

"The condemnation asked will be ordered upon the ground that the directions printed did not comply with the statute, upon the ground that they

were inadequate.

"I am not holding that Ri-Co Tablets are worthless. That issue actually was not presented to me. The Court has the authority, in its discretion, to permit the claimant to relabel these tablets; but certainly for the Court to allow claimant which has violated the law to relabel tablets, the claimant should make an affirmative showing that appeals to the judgment or conscience or both of the Court. No showing whatsoever has been made. It is conceded that the claimant has been held repeatedly to have violated the law, either as to these tablets or other preparations. The claimant has not attempted to persuade me that the tablets are good and that there would be any loss to humanity or posterity if I allow condemnation to be effected.

Claimant has relied solely upon the Willard Tablet case, which is a holding of the Northern Circuit and not binding on me, and which is contrary to a holding of this Circuit which does control.

"I know no good reason that I should require the Government to turn over these tablets for relabeling. Judgment and order will be presented in con-

formity with my announcement.

"Counsel, there was something you wished to say?"

Mr. HAUERKEN. "I presume it is too late inasmuch as your Honor has announced judgment. I do feel your Honor has erroneously construed the Research Laboratories Company case. I do not know whether your Honor wants me to be heard on this or not, but I would like to show my views

The COURT. "Well, counsel, I told you I am quite familiar with that case. I am speaking now informally. It is not a part of my decision. I thought at the time I rendered decision in Tacoma that I was right. It might not be very hard for you to convince me that the Circuit Court was mistaken, but the Circuit Court reversed me and I am bound by what it said and certainly it said what I have quoted from it, because I read it verbatim. I have no quarrel with that portion of the Circuit Court's holding. I think, as I pointed out before to you, I have held the libel was so crudely and inexpertly drawn that it had no right to be considered by the Court and I dismissed it. The Circuit Court of Appeals in reversing me admitted the following:

The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce.

"But the Circuit Court of Appeals held that the crudeness and lack of expertness in the drawing of the libel, while not to be commended, was not as fatal as I thought it was. But I am satisfied now. Upon the problem you present I have disagreed directly with you and disagreed directly with the

doctrine of the Willard case on which you relied."

Mr. HAUERKEN. "The point I make in that, that violation, if any, was a violation of the Federal Trade Commission Act and therefore there could be no prosecution under the Food and Drug Act, as I recall that case. The question was whether or not the pamphlets had accompanied the article in interstate commerce. Wasn't that the case where it was held common origin, common destination, and approximately a shipment at the same time constituted a libel? I think that is the case I have in mind."

The COURT. "Well, whatever was there at issue, the Circuit Court of Appeals announced the doctrine for this Circuit that answered your argument far better than any counsel could hope to answer it, and the Circuit Court of Appeals for the Fifth Circuit seemed to think that that doctrine was appropriate because, as I say, it disregarded the decision in 113 Fed. (2d) the court

in the Willard case relied on."

Mr. Hauerken. "My concept of that case is that a person could violate both acts, and I think that is what those cases hold, that by the one action

you would be in violation of both acts.'

The COURT. "I have no question of that, counsel, but both courts say in an independent proceeding on different showings the court is not bound by what the Federal Trade Commission may do, and that is particularly true when what the Federal Trade Commission did, in so far as it did anything, was on stipulation; and most particularly true when the Federal Trade Commission didn't do anything, but just merely negatively said that its order was not to be construed as stopping you from doing something."

Mr. HAUERKEN. "I merely wanted to present that point, your Honor. I have

no desire to draw the matter out."

The COURT. "The Court will say this: It has been very interested in the presentation by counsel on both sides. Counsel on each side have been very helpful to the Court and have ably presented their various matters. I am sure I understood the presentation of counsel for claimant. Under the law as I see it, and the facts as presented, I am holding against him. He may be right, but I do not think so. I thank counsel on both sides for your assistance to the Court.

"That is all."

In accordance with the above opinion, the court, on November 29, 1949, handed down its findings of facts and conclusions of law and on the same day entered a decree providing for condemnation and destruction of the product. Pursuant to the decree, the United States marshal destroyed the product on December 14, 1949. The notice of appeal was filed by the claimant on December 16, 1949. A motion to dismiss the appeal then was filed on behalf of the Government in the United States Court of Appeals for the Ninth Circuit on the ground that the product was no longer in existence and that the case therefore had become moot. On April 3, 1950, the appellate court denied the motion, without prejudice to its renewal by the Government if so advised on the hearing of the case on its merits. The case was argued before the court of appeals on October 18, 1950, and on November 20, 1950, the court handed down the following opinion affirming the judgment of the district court:

Bone, Circuit Judge: "Appellee filed a libel under which it seized appellant's drug here involved (33 bottles of Ri-Co Tablets) charging therein that the drug was 'misbranded' in violation of 21 U. S. C. A. Sec. 352 (f) (1) of the Federal Food, Drug, and Cosmetic Act (referred to hereafter as the Act). The specific ground of complaint was that the 'labeling' of the drug failed to bear adequate directions for use since it did not state the purpose or condition for which the drug was intended. The only directions for use on the label attached to the bottle read as follows: 'Three tablets with a cupful of, hot water. Take four times daily. Before meals and on going to bed.'

"At the hearing below two newspaper advertisements from daily publications in large cities were introduced. These ads show that appellant's drug was there represented and recommended by appellant for use in the treatment, mitigation, and cure of arthritis and rheumatism. The two advertisements

read as follows:

ROCKY MOUNTIAN NEWS Tuesday, Oct. 1, 1946-

ARTHRITIS
RHEUMATISM
RICO TABLETS
Another Alberty
Product

Do you suffer from ARTHRITIS or RHEUMATISM, two of the most painful ailments that afflict mankind?

These ailments arise from the same underlying cause—two [sic] much acidity that permits deposits of urates in joints or muscles that cause excruciating pain.

Science has spent many years searching for remedies for these ailments. If you have tried many remedies without relief TRY RICO, a formula discovered by a famous Homeopathic physician for relief of the pains of ARTHRITIS and RHEUMATISM. For over 15 years this formula has been used by many eminent Homeopathic Physicians.

RICO is harmless and does not upset the digestive tract or affect the heart.

275 TABLETS_____\$2.00
In Colorado, include 2% state sales tax
SENT POSTPAID WHEN REMITTANCE ACCOMPANIES ORDER.
LEEDS HEALTH HOUSE
Under new ownership
Ethel Barnes and Helen Olson

Ethel Barnes and Helen Olson 725 15th St. KE. 9214 2 doors from Denver Dry Goods.

SAN FRANCISCO CHRONICLE Monday, June 7, 1948 Page 13-

TROUBLED with Symptoms of ARTHRITIS RHEUMATISM? ALBERTY'S RICO TABLETS WHY SUFFER FROM THE PAINS OF THE SYMPTOMS OF ARTHRITIS AND RHEUMATISM WHEN RICO MAY GIVE YOU AMAZING PALLIATIVE RELIEF LIKE IT HAS DONE FOR COUNTLESS OTHERS?

Some 25 years ago a famous Homeopathic Physician attacked this problem from the homeopathic point of view. He combined certain ingredients according to the theories of homeopathy for relieving certain symptoms of arthritis and rheumatism. This formula has stood the test of time and it has been widely used by many Homeopathic Physicians.

ALBERTY'S RICO TABLETS

Rico is made by the same formula originated by the famous Homeopathic Physician. And, according to the principles of Homeopathy, improves the symptoms of muscular or ligamentous pain and stiffness due to ARTHRITIS or RHEUMATISM except when accompanied by a febrile condition. They are not a SEDATIVE; do not upset the DIGESTIVE TRACT OR AFFECT THE HEART.

> Try RICO todayan ALBERTY PRODUCT \$1.00, TWO WEEKS' SUPPLY. ECONOMY SIZE, \$2.00 San Francisco HEALTH FOODS Store 415 Sutter St. Ex. 2-8477

"Appellant appeared as claimant of the drug and filed exceptions to the libel. In essence the exceptions were that the Act does not require the labeling of a drug to state the disease condition for which it is to be used. In this connection it contended that the misbranding here charged was merely a failure to include upon the label of the container information to consumers which was not required by the Act to be included thereon either as directions for its use or otherwise. As a consequence the libel failed to state a cause of action because the alleged misbranding was not a misbranding at all. Appellant's exceptions were overruled by the trial court. Appellant's subsequent answer to the libel admitted that the seized Ri-Co Tablets were a drug that had been shipped in interstate commerce.

"After the answer, appellee filed a motion for summary judgment which asserted (1) there were no facts in dispute and (2) the only legal issue had been decided in favor of appellee when the lower court overruled claimant's exceptions to the libel. It supported this motion by (1) an affidavit of a Food and Drug representative incorporating photostats of the complete labeling on the drug container and the two newspaper advertisements above noted, and (2) the affidavits of four physicians (licensed to practice in California) attesting to the complete worthlessness of Ri-Co Tablets in the treatment or cure of arthritis or rheumatism or their symptoms.1

"Appellant filed no counter-affidavits, and after hearing the court granted appellee's motion for summary judgment, made and entered Findings and Conclusions and a Decree pursuant thereto. The Decree condemned the drug, ordered it destroyed 2 and awarded certain costs to appellee. The appeal is from this Decree.

'In urging reversal appellant presents five claims of error committed by the lower court and it simplifies the problem in this case by stating that these errors relate to only two basic issues. Claims 4 and 5 both relate to the pro-

Despite the physicians' affidavits the lower court refused to consider the question

¹ Despite the physicians' affidavits the lower court refused to consider the question of the therapeutic qualities of the drug. It held that the misbranding charge in the libel was sustained, and this ruling presents the controlling issue on this appeal.
² Pursuant to the decree the drug in question was destroyed by the United States Marshal. Because of the Ri-Co Tablets are no longer in existence, appellee's brief suggested absence of jurisdiction to entertain this appeal, but on argument appellee advised the court that it was not urging this point and we disregard it. In this connection we note that appellant did not seek a stay of the order of destruction.
³ In its findings the court sets forth that appellant had proposed to consent to a decree of condemnation provided permission was given to relabel the drug so as to conform with certain language in a Federal Trade Commission Order. In the exercise of its discretion (under Sec. 334 (d) of the Act) the court denied this privilege. Appellant states that it does not question that ruling on this appeal and it is not in issue here.

cedural question of whether a summary judgment was proper in this case. Claims of error, 1, 2 and 3 all relate to the question of whether or not the Act requires that the directions (on the bottles) for the use of the tablets include a statement of the conditions for which the tablets are used.

"In appellant's argument on the issues as thus narrowed, it says:

With the exception therefore of the procedural issues of whether a summary judgment can be granted in a condemnation proceeding and whether a summary judgment should have been granted in this proceeding, the only issue before this court is the issue of whether the Act requires that the directions for the use of the tablets include a statement of the conditions for which they are used.

The directions printed on the label of Ri-Co Tablets are adequate for their use in all conditions for which they are prescribed, recommended, suggested, or commonly and effectively used. The Act does not require a label to include a statement of those conditions and the decree should accordingly be reversed with instructions to dismiss the libel. In the alternative, the decree should be reversed, and the question of whether the directions are adequate for the intelligent and effective use of the tablets should be left to the determination of the jury. [Emphasis supplied.] [As later appears, this reference in the last sentence refers to the propriety of the summary judgment in this case.]

"As respects the legal sufficiency of the label appearing on its bottle, appellant clarifies its position by the further argument:

The Government * * * contends that no information could be more essential to the consumer regarding a drug which he can purchase without prescription than a statement of the conditions for which the drug is used. We agree that no one is likely to purchase a drug without knowing the conditions for which the drug is used. That knowledge, however, must be imparted to the consumer by means other than the label. He must have it before he gets close enough to the label to be able to read its fine print. In other words, he will not buy the drug unless he learns of the conditions for which it is used from sources outside the label, as by prescription, recommendation, suggestion, or common and effective usage. By the time he sees the label, he needs only to be protected by being told how to use the drug for the condition for which he is purchasing it. If "4 times daily" is an adequate direction for the use of the drug in that condition, the label complies with the Act irrespective of whether it refers to that condition. [Emphasis supplied.]

"The foregoing argument conclusively shows that appellant relied exclusively upon these 'outside sources,' namely, the newspaper advertisements, to provide *all* of the information which could possibly enlighten prospective purchasers of its drug concerning 'the conditions' for which the drug was to be used by them.

"Appellant also offers some reasons for its failure to include on the bottle label nothing more than the dosage recommended. In substance it argues that: a statement of all conditions or symptoms for which the drug is used would be so long that it could not be included within the limits of the label. While it is true that Sec. 352 (f) (1) requires 'directions for use' on the labeling, and Sec. 321 (m) defines 'labeling' as including the 'label' on the immediate container and all other 'accompanying' literature, still this use of the more inclusive term 'labeling' is nullified by Sec. 352 (c) which deems a drug misbranded unless all information required to appear on the labeling be placed thereon in such manner as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

"The arguments in the preceding paragraph lack persuasiveness and merit.

THE BASIC ISSUE

"Two recent cases present a material bearing on the issue before us. Kordel v. United States, 335 U. S. 345 and United States v. Urbuteit, 335 U. S. 355. The Kordel case involved the shipment and sale of a drug—a charge of misbranding was made because of certain representations in 'accompanying' leaflets, circulars and pamphlets supplied by Kordel, and distributed by his vendors to consumers and users. These 'accompanying' documents contained statements relative to the use and efficacy of the drugs. As we understand

the doctrine announced in these cases it is that where literature of the character above indicated is shipped in interstate commerce and distributed to consumers as part of an integrated distribution program, the literature which thus accompanies the drug and is distributed with it, constitutes an essential supplement to the label attached to the package containing the drug although this literature may have been shipped separately and at a different time than the drug. This process made the product and the literature 'interdependent' so far as 'labeling' is concerned. In short, the supplemental literature was considered a part of the label on the drug container.

"In the case at bar we face a different set of facts. Appellant did not resort to the distribution of any sort of 'literature' to ultimate purchasers as a 'supplement' to its package label. Neither did it distribute such 'literature' to purchasers, actual or prospective, to promote sales and to describe and advertise the therapeutic qualities of its drug. Appellant used only the newspaper advertisements and we think that it cannot be said that these advertisements 'accompanied' appellant's drug into interstate commerce, and were 'distributed' by vendors, or otherwise, to ultimate purchasers of the drug as part of an 'integrated distribution program.' On the 'labeling' issue, this

distinction should be borne in mind.

"What we have already said leads us to disagree with appellant's contention that by employing these 'remote' newspaper advertisements it fully supplied a legally adequate 'labeling' which described the use of the drug in the treatment or alleviation of arthritic or rheumatic conditions. It seems to us that supporting appellant's views would be a long and drastic step toward nullifying what we regard as salutary protective features of the act which Congress designed to control and regulate the sale of drugs to a helpless public-helpless because it is uninformed. (See comment on this phase of the law in United States v. Various Quantities—Instant Alberty Food, 83 F. Supp. 882.) The logic of the Kordel and Urbuteit cases would seem to repel the conclusion that the therapeutic claims made only in random newspaper advertisements, must be considered and deemed to be a part of, and to be 'accompanying' and 'supplementing,' the brief dosage statement appearing on the bottles containing appellant's drug. There is no hint in the record that these advertisements were reproduced in pamphlet or leaflet form and shipped with the drug on its interstate journey from appellant to its vendors to be distributed to ultimate consumers. No claim is made that the reading matter in the newspaper advertising appeared in any sort of literature (pamphlet, etc.) which was made available by vendors to purchasers of the drug.

"A wholly justifiable inference is that many of those who suffer from pains of arthritis and rheumatism—and they are legion—never heard of Ri-Co Tablets, and undoubtedly never saw, or had a chance to see, appellant's newspaper advertisements. It is certain that as to them, these advertisements gave absolutely no notice of the existence of the drug, its dosage, uses and therapeutic qualities. We proceed upon the assumption that the 'adequate directions for use' mandate of Sec. 352 (f) (1) requires that all who might want to use a drug to relieve the pains of arthritis and rheumatism are at least entitled to a chance to somewhere find and examine a 'label' which is complete enough to give them information which would lead them to purchase a drug for that purpose, or, in other words, provide sufficient information at the time of purchase upon which intelligent determination might be made as to whether the drug is one which is prescribed, recommended, or suggested for their particular form of arthritis or rheumatic ailment. We are persuaded

that the law requires this much.

"Since the kind of complete information we have indicated was not made available to the general run of victims of arthritis and rheumatism by a proper and adequate 'labeling' of appellant's drug, we must hold that it was 'misbranded' under Sec. 352 (f) (1) of the Act. This for the reason that what appellant insists is a proper and adequate 'labeling' falls far short of legal requirements. It failed to bear 'adequate directions for use' since it did not state the purpose or condition for which the drug was intended.

THE ISSUE OF SUMMARY JUDGMENT

"Appellant contends that a summary judgment was an 'improper' remedy and may not be obtained in this case because appellee is not 'a party seeking to

recover on a claim * * * or to obtain a declaratory judgment' (under Rule 56, F. R. C. P.) this being a condemnation proceeding and not an orthodox civil action. The contention rests on the language of the Act (Sec. 334 (b)) prescribing that procedure in condemnation cases 'shall conform, as nearly as may be, to the procedure in Admiralty.' [Emphasis supplied.] The argument is predicated upon the holding in two district court cases.'

"The heart of this part of appellant's argument is presented in the statement that 'this case presents a genuine issue of fact as to which Alberty is entitled [as it requested] to a jury trial' (as in ordinary civil cases)—this because the pleadings raised the question of whether directions given by Alberty for the use of the tablets are 'adequate for its intelligent and effective use.' Appellant supports this contention by reliance on two cases from this Circuit but

we think that they do not aid its case.

"Because of the nature of seizure cases, like the one at bar, a question has arisen in the past as to whether Admiralty rules apply in such seizure actions under the Act. After the enactment of the present statute the Sixth Circuit (United States v. 935 Cases, etc., 136 F. 2d 523) held that proceedings of the character here involved are not intended to be likened to those in admiralty beyond the seizure of the property by process in rem under the statutes. See also 443 Cans of Frozen Egg Product v. United States, 226 U. S. 172, 183. As appellee points out, an imposing group of authorities now support the proposition that despite a contrary holding in certain of the earlier cases dealing with enforcement of the 1938 Act, the better rule is that the Rules of Civil Procedure apply in these seizure actions as soon as the property proceeded against has been seized. We prefer to accept and adopt the principle announced in these later cases and hold that the Admiralty rules do not apply in seizure actions like this beyond apprehension of the property. The lower court did not err in entering its Summary Judgment under Rule 56 (a) unless it can be said that the labeling here involved was not a misbranding of the drug, a view we have refused to accept.

"The record clearly discloses that a genuine issue of fact was not presented to the court. The basic question presented and properly considered by the lower court was whether the labeling on the drug failed to bear 'adequate directions for use' in violation of Sec. 352 (f) (1) of the Act. Having concluded, as a matter of law, that the labeling of the drug wholly and completely failed to conform to the requirement of this Section, the court properly held that the drug was misbranded. In this posture of the case it presented only a question of law and this clearly justified entry of the summary judgment

as authorized in cases where the civil rules apply.

"The lower court correctly decided the case and its judgment is affirmed."

3311. Misbranding of diathermy device. U. S. v. 19 Devices * * * (F. D. C. No. 25693. Sample No. 37847-K.)

LIBEL FILED: October 13, 1948, Western District of Washington.

ALLEGED SHIPMENT: On or about July 6 and September 15, 1948, by David Bogen Co., Inc., from New York, N. Y.

⁴ United States v. 720 Bottles, etc., 3 F. R. D. 466 (1944); United States v. 149 Gift Packages, etc. 52 F. Supp. 993 (1943).

⁵ Gifford v. Travelers Protective Ass'n., 153 F. 2d 209, and Koepke v. Fontecchio, 177 F. 2d 125.

⁶ See further: Eureka Productions, Inc. v. Mulligan, 2 Cir., 108 F. 2d 760, 761; United States v. 88 Cases, etc., 5 F. R. D. 503 (1946); United States v. 300 Cans, etc., 7 F. R. D. 36 (1946); United States v. 305 Cases, etc., 6 Cir. (1943), 136 F. 2d 523, 525, cert. denied 220 U. S. 778; United States v. 20 Cases, etc., 77 F. Supp. 231 (1947); C. C. Co. v. United States, 5 Cir. (1945), 147 F. 2d 820, 824; United States v. 5 Cases, etc. 2 Cir. (1950) 179 F. 2d 519, 522, 524, notes 9 and 15. In this case the court said: "It now appears well established that the Rules of Civil Procedure do apply to condemnation proceedings." And see cases cited in Fed. Prac. and Procedure, Barron and Holtzoff, Vol. 1, page 219 (case cited as being in 8 F. R. D. 81 is at same page in Vol. 9, F. R. D.).

PRODUCT: 19 diathermy devices at Seattle, Wash. The device consisted of a cabinet containing radio tubes, transformer, resistors, and adjustable plate condensers. Connected to the device were two 8" x 10" diathermy pads, which transmit short electrical waves to the portion of the body to be treated.

Label, in Part: "David Bogen Co., Inc., New York 12, New York Model No. 5-A * * * Short Wave Diathermy."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of sinus, colds, etc., elbow, wrist, leg, stiff neck, sprained ankle, hand, shoulder, knee, and upper back and lower back, which were the parts of the anatomy and abnormalities to affect and treat, for which the article was offered in its labeling, namely, in an accompanying leaflet headed "Illustrations of Pad, Mask, Cuff and Cable Placement for Typical Treatment Employing Bogen Portable Short Wave Diathermy Model 5-A."

Disposition: November 18, 1950. George B. Quinn, Seattle, Wash., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3312. Adulteration and misbranding of surgical dressing. U. S. v. Surgical Dressings, Inc. Plea of guilty. Fine, \$250. (F. D. C. No. 29427. Sample Nos. 30230-K, 30240-K, 33682-K to 33684-K, incl.)

Information Filed: October 3, 1950, District of Massachusetts, against Surgical Dressings, Inc., Boston, Mass.

ALLEGED SHIPMENT: Between the approximate dates of August 25 and November 12, 1949, from the State of Massachusetts into the State of California.

LABEL, IN PART: "Sterilastic Dressing Bandage."

Nature of Charge: Adulteration, Section 501 (c), the purity and quality of the article differed from that which it purported and was represented to possess since it purported to be, and was represented as, a sterile product, whereas it was not a sterile product but was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the statements in the labeling of the article which represented and suggested that the article was a sterile product were false and misleading.

DISPOSITION: December 12, 1950. A plea of guilty having been entered, the court imposed a fine of \$250.

3313. Adulteration and misbranding of clinical thermometers. U. S. v. 9 Gross * * * (F. D. C. No. 29366. Sample No. 81854-K.)

LIBEL FILED: June 21, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about May 9, 1950, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 9 gross of *clinical thermometers* at Miami, Fla. Examination of 24 thermometers showed that 5 failed to comply with the Commercial Standard C. S. 1-32 since 2 failed to repeat readings and 3 did not give readings of the accuracy required by C. S. 1-32.

LABEL, IN PART: "Car-Nor" or "Cardinal,"

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess since the article would not give accurate readings.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to an article which would not give accurate readings: "This certifies that the enclosed thermometers have been tested on the above date at 98°, 102° and 106° F. and are correct within plus or minus 2/10 F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–32 Department of Commerce). The enclosed thermometers are guaranteed to be of absolute accuracy." Further misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

DISPOSITION: October 12, 1950. Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

- 3314. Misbranding of Guardian vitamin A capsules, Guardian D/E Plex capsules, and Guardian Se-Bex tablets. U. S. v. Vitamin Industries, Inc., and Joseph L. Zweiback. Pleas of nolo contendere on counts 1 and 2 for the corporation and on count 2 for the individual. Fine of \$125 against each defendant. (F. D. C. No. 28156. Samples Nos. 20070-K, 20071-K.)
- Information Filed: May 15, 1950, District of Nebraska, against Vitamin Industries, Inc., Omaha, Nebr., and Joseph L. Zweiback, president of the corporation.
- ALLEGED SHIPMENT: On or about January 9 and 19, 1949, from the State of Nebraska into the State of Iowa.
- LABEL, IN PART: "Guardian Capsules Vitamin A 5,000 USP Units," "Guardian Capsules D/E Plex * * * Each Capsule Contains: Vitamin D 25,000 USP Units Vitamin B₁ 3 Mgm. Vitamin B₂ 2 Mgm. Vitamin C 37.5 Mgm. Niacinamide 20 Mgm. Calcium Pantothenate 1 Mgm. Vitamin B₆ 100 Mcg. Alpha Tocopherol 10 Mgm.," and "Guardian Tablets Se-Bex Vitamin C with B Complex * * * Each Tablet Contains: Vitamin C 125 milligrams Vitamin B₁ 1.5 milligrams Niacinamide 10 milligrams."
- Nature of Charge: Guardian vitamin A capsules and Guardian D/E Plex capsules. Misbranding (count 1), Section 502 (a), certain statements in an accompanying circular entitled "Price List April 1948" were false and misleading. The statements represented and suggested that the capsules would be efficacious in the cure, mitigation, and treatment of arthritis, primary fibrositis, and muscular rheumatism, whereas the capsules would not be efficacious for such purposes.

Guardian Se-Bex tablets. Misbranding (count 2), Section 502 (a), certain statements in an accompanying circular entitled "Price List April 1948" were false and misleading. The statements represented and suggested that the tablets would be efficacious in the cure, mitigation, and treatment of hay fever

^{*}See also Nos. 3309, 3312, 3313.

and allergic disorders, whereas the tablets would not be efficacious for such purposes.

Disposition: November 24, 1950. Pleas of nolo contendere having been entered on behalf of the corporation to counts 1 and 2 and on behalf of the individual to count 2, the court imposed a fine of \$125 against each defendant. Count 1 against the individual was dismissed.

3315. Misbranding of Sodeene Osmotic Bath. U. S. v. 26 Cartons, etc. (F. D. C. No. 29388. Sample Nos. 71229-K to 71231-K, incl.)

LIBEL FILED: July 17, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about June 20 and 28 and July 5, 1950, by the Consultants Laboratories of New Jersey and by H. H. Marshall, from Garden City, N. Y.

Product: 26 cartons, each containing 8 24-ounce packages, of Sodeene Osmotic Bath at Bellflower, Calif., together with a number of circulars entitled "Sodeene A New Type Of Therapy."

Examination indicated that the product consisted essentially of sodium carbonate, a wetting agent such as sodium lauryl sulfate, and an extract of plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading. These statements represented and suggested that the article was effective in the treatment of deep-seated infection, arthritis, sinusitis, rheumatic fever, inflammatory rheumatism, sciatica, neuritis, and many infections in the body fluids, including those of a virus nature, and that the article would be effective in bringing about a reabsorption of calcium deposits and in preventing polio, whereas the article was not effective in the treatment of the conditions stated and implied.

Further misbranding, Section 502 (a), the labeling, namely, the accompanying circular, contained statements which represented and suggested that the product had been approved by the Food and Drug Administration as effective in the treatment of the disease conditions stated, which statements were misleading since the Food and Drug-Administration had not approved the product for the treatment of such disease conditions.

DISPOSITION: August 17, 1950. Default decree of condemnation and destruction.

3316. Misbranding of Facializer device, DermaCulture Contour Mold device, DermaCulture Formula No. 103, cleansing lotion, herbal astringent, granular cleanser, DermaCulture Formula No. 102, and DermaCulture Formula No. 104. U. S. v. 1 Facializer Device, etc. (F. D. C. No. 27639. Sample Nos. 55233-K, 55252-K to 55256-K, incl., 55258-K, 55259-K.)

LIBEL FILED: August 22, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 6 and December 2, 1948, and March 8, April 7, July 25, and August 5, 1949, by DermaCulture, Ltd., from Los Angeles, Calif.

Product: 2 Facializer devices with accessories, 20 DermaCulture Contour Mold devices, and a number of drugs at Kansas City, Mo., together with a manual entitled "DermaCulture NRB. 339." The drugs consisted of 26 2-ounce bottles of DermaCulture Formula No. 103, 24 bottles of cleansing lotion, 24 bottles of herbal astringent in 4-ounce, 8-ounce, and 1-pint sizes, 20 4-ounce jars of granular cleanser, 16 1-ounce bottles of DermaCulture Formula No. 102, and

16 1-ounce bottles of DermaCulture Formula No. 104 (also called "Steaming Lotion").

Examination disclosed that the Facializer device was an electronic device designed to produce a vacuum and to transform commercial electric current to a galvanic current of low voltage and low amperage; that the DermaCulture Contour Mold device consisted of sponge rubber, with adjustable fasteners for holding under the chin; that the DermaCulture Formula No. 103 consisted essentially of water, iron, zinc, and magnesium compounds, including sulfates and citrates; that the cleansing lotion consisted essentially of an emulsion of fatty materials and water perfumed with methyl salicylate; that the herbal astringent consisted essentially of alcohol, glycerin, perfumes, and color; that the granular cleanser consisted essentially of talc, zinc oxide, starchy material, glycerin, and perfume; that the DermaCulture Formula No. 102 consisted essentially of iron and sodium compounds, salicylates, and phosphates; and that the DermaCulture Formula No. 104 consisted essentially of water, extracts of plant materials, and formaldehyde.

Nature of Charge: Misbranding, Section 502 (a) certain statements appearing in the manual recommending the use of the Facializer device with one or more of the drugs were false and misleading. The statements implied and suggested that the device and the drugs would constitute an effective treatment for facial blemishes, acne, and scars; that they would give the user a firm youthful complexion; and that they would relieve nervous tension and pain. The device and the drugs would not be an effective treatment for such purposes.

Further misbranding, Section 502 (b) (1), the *DermaCulture Formulae Nos.* 102, 103, and 104 failed to bear labels containing the place of business of the manufacturer, packer, or distributor.

Further misbranding Section 502 (e) (2), the drugs with the exception of the *cleansing lotion* and the *granular cleanser*, were not designated solely by a name recognized in an official compendium, and they were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient; and with respect to the *herbal astringent*, the label also failed to bear the quantity, kind, and proportion of alcohol contained therein.

Further misbranding, Section 502 (a), the following statements appearing in the direction sheet entitled "Contour Mold," which related to the *Derma-Culture Contour Mold device*, were false and misleading since the device was not effective in accomplishing the results suggested and implied: "Contour Mold. For correction of double chin, flabby jaw muscles and crepy throat. * * * acts as a soft tissue cast." Further misbranding, Section 502 (b) (1), the label of the *Derma-Culture Contour Mold device* failed to bear the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: November 10, 1949. DermaCulture, Ltd., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling, under the supervision of the Federal Security Agency.

3317. Misbranding of Roll a Ray heat massage device. U. S. v. 100 Devices * * * (F. D. C. No. 26258. Sample No. 42206–K.)

LIBEL FILED: January 17, 1949, Northern District of Illinois.

ALIEGED SHIPMENT: On or about November 1, 1948, by the Electric Cord Co., from New York, N. Y.

PRODUCT: 100 Roll a Ray heat massage devices at Chicago, Ill. Examination showed that the device consisted of a brown plastic molded case with a handle attached. The case enclosed a 60-watt light bulb and two rubber rollers placed at either end of the bottom part of the case. The rollers contacted the body for massaging purposes, and the light bulb furnished the heat. A plastic grid was fitted over the bulb to protect the body from contact with the lamp.

Label, IN Part: "Roll a Ray Heat Massage With Infra Red Division Of The O. A. Sutton Corporation Wichita, Kansas."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Home Reducing and an Aid in the Relief of Discomforts Arising from Rheumatism, Lumbago, Muscular Aches, Physical Aches * * * for Health and Beauty * * * to remove fatty tissues. Many varied ailments respond to application of heat and massage * * * for loosening muscles and assisting in driving fatty tissues away" were false and misleading since heat and massage are not adequate treatments for such purposes.

Disposition: May 10, 1950. The Fair Co., Chicago, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for modification and relabeling under the supervision of the Federal Security Agency. The devices were modified by replacing the bulbs contained therein with 30-watt bulbs and by inserting a foil reflector in the grid; they then were relabeled in compliance with the law.

3318. Misbranding of plastic suits. U. S. v. 488 Cartons * * *. (F. D. C. No. 29404. Sample No. 81210-K.)

LIBEL FILED: July 18, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 12 and 24 and May 4, 1950, by the Advance Mfg. Co., from Mount Vernon, Ind.

PRODUCT: 488 cartons each containing a plastic suit and a copy of a circular entitled "Fashion Form" at Philadelphia, Pa. Examination showed that the suit was a coverall made of plastic, with elastic bands at wrists, ankles, and neck. It was to be worn to induce perspiration.

Label, in Part: (Carton) "Fashion Form Style 3800 Color Clear."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the device were false and misleading: (Carton) "Fashion Form" and (circular) "Fashion Form * * * An aid to reducing * * * You may find your health improved * * * your Fashion-Form is not only an aid to losing weight but also contributes to your general health by inducing perspiration." Such statements represented and suggested that the device when used as directed was effective for bringing about a reduction of body weight, resulting in improved health and fashionable form, whereas the device was not capable of fulfilling such promises of benefit.

DISPOSITION: October 9, 1950. Sears, Roebuck & Co., Chicago, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3319. Misbranding of Security Special Udder Formula. U. S. v. Jennie Canter and George Canter. Pleas of guilty. Fine of \$250 against George Canter; imposition of sentence suspended against Jennie Canter and this defendant placed on probation for 1 day. (F. D. C. No. 25569. Sample No. 4804–K.)

INFORMATION FILED: April 26, 1950, Southern District of New York, against Jennie Canter and George Canter, New York, N. Y.

ALLEGED SHIPMENT: On or about January 9, 1948, from the State of New York into the State of Massachusetts.

Label, in Part: "Security Special Udder Formula * * * Åctive Ingredients: Carbolic Acid 2%—Zinc Oxide—Alum—Ichthammol—Lead Plaster * * * Manufactured for and Distributed by Security Remedies Co., 144 W. 27th St., New York 1, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a paper poster and a number of circulars entitled "Save the Udder and You Save the Cow," were false and misleading. The statements represented and suggested that the article was an antiseptic healing ointment; that it would be efficacious to help keep milk production at a peak level; that it would be efficacious in the treatment of swollen udders, red, painful, sore, infected, inflamed, and caked udders, and bruises, and other udder troubles; that it would be efficacious in the treatment of mastitis; and that it would be efficacious to stop pain. The article was not an antiseptic healing ointment, and it would not be efficacious for the purposes represented.

DISPOSITION: October 25, 1950. Pleas of guilty having been entered, the court imposed a fine of \$250 against George Canter, suspended the imposition of sentence against Jennie Canter, and placed her on probation for 1 day.

3320. Misbranding of Dr. Martin's Sulfa Du. U. S. v. 78 Bottles * * * (F. D. C. No. 28542. Sample No. 64528-K.)

LIBEL FILED: January 27, 1950, District of South Dakota.

ALLEGED SHIPMENT: On or about November 19, 1949, from Sibley, Iowa.

PRODUCT: 78 1-quart bottles of Dr. Martin's Sulfa Du at Sioux Falls, S. Dak., in possession of the Martin Laboratories (Carl Ebert, owner).

RESULTS OF INVESTIGATION: The product was transported unlabeled from Sibley, Iowa, by Carl Ebert in his personally owned car. The labels of the product were affixed at destination.

Label, in Part: "Dr. Martin's Sulfa Du * * * Active Ingredients: Sulfathiazole in soluble acid form, 22.2 gr. per fl. oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. These statements represented and suggested that the article when added to drinking water as directed, was effective in the treatment and control of the disease of poultry known as infectious coryza and was effective to provide adequate blood sulfonamide levels for the treatment of infectious coryza in poultry. The article when added to drinking water as directed, was not effective for the purposes stated and implied. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 28, 1950. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3301 TO 3320

PRODUCTS

N. J. No.	
Amphetamine, Dextro-, hydro-	Guardian vitamin A capsules,
chloride tablets 3307	Guardian D/E Plex capsules,
phosphate tablets 3305	and Guardian Se-Bex tablets_ 3314
Astringent, herbal3316	Herbal astringent 3316
Benzedrine Sulfate tablets 3302, 3303	Martin's, Dr., Sulfa Du 3320
Cleansing lotion 3316	Nembutal Sodium capsules 3304
Cosmetics (subject to the drug	Nurse Dencker's ointment 13309
provisions of the Act):	Ointments 13309, (veterinary) 3319
DermaCulture Formulae Nos.	Osmotic Bath, Sodeene 3315
102, 103, and 104; cleansing	Pentobarbital sodium capsules
lotion; granular cleanser;	3305, 3306
and herbal astringent 3316	Phenobarbital tablets 3307, 3308
DermaCulture Contour Mold de-	Plastic suits 3318
vice, DermaCulture Formula	Reducing, device for3318
No. 102, DermaCulture Form-	Ri-Co tablets² 3310
ula No. 103, and DermaCul-	Roll a Ray heat massage device 3317
ture Formula No. 104 3316	Seconal Sodium capsules 3301-3305,
Devices 3311, 3313, 3316–3318	3307
Dexedrine Sulfate tablets 3304	Security Special Udder Formula_ 3319
Dextro-amphetamine hydrochlo-	Sodeene Osmotic Bath 3315
ride tablets3307	Sulfa Du, Dr. Martin's 3320
Diathermy device3311	Sulfadiazine tablets 3305, 3307
Diethylstilbestrol tablets 3308	Surgical dressing 3312
Dressing, surgical3312	Thermometers, clinical 3313
Facializer device3316	Veterinary preparations 3319, 3320
Granular cleanser 3316	Vitamin preparations 3314
SHIPPERS, MANUFACTUR	ERS, AND DISTRIBUTORS
N. J. No.	N. J. No.
Advance Mfg. Co.:	Cardinal Thermometer Co.:
plastic suits 3318	clinical thermometers 3313
Alberty Food Products Co.:	Consultants Laboratories of New
Ri-Co tablets²3310	Jersey:
Alcorn, M. E., and W. V.:	Sodeene Osmotic Bath 3315
Nurse Dencker's ointment ¹ 3309	Cowan, Jack:
Bogen, David, Co., Inc.:	pentobarbital sodium capsules,
diathermy device 3311	Seconal Sodium capsules,
Budner's Pharmacy:	amphetamine phosphate tab-
Seconal Sodium capsules and	lets, and sulfadiazine tab-
Benzedrine Sulfate tablets_ 3303	lets 3305
Canter, George, and Jennie:	Dencker Products. See Alcorp,
Security Special Udder For-	M. E., and W. V., and Stan-
mula 3319	lov W G

 ⁽³³⁰⁹⁾ Permanent injunction issued.
 (3310) Seizure contested. Contains opinions of the courts.

27	T 37-		T 37.
DermaCulture, Ltd.:	. J. No.	Marshall, H. H.:	. J. No.
Facializer device, DermaCul-		Sodeene Osmotic Bath	3315
ture Contour Mold device,		Martin Laboratories:	0010
DermaCulture Formula No.		Dr. Martin's Sulfa Du	3320
103, cleansing lotion, herbal		Moore, J. W.:	0020
astringent, granular cleans-		pentobarbital sodium capsules_	3306
er, DermaCulture Formula		Owl Drug Co. See Smith, Ernest.	99.0
No. 102, and DermaCulture		Piszczek, J. P.:	
Formula No. 104	3316	Seconal Sodium capsules and	
Drummond, C. C.:	9910	Benzedrine Sulfate tablets_	3302
Seconal Sodium capsules, Dex-		Piszcek's Pharmacy. See Pisz-	0002
edrine Sulfate tablets, and		czek, J. P.	
Nembutal Sodium capsules_	3304	Ridberg, Morris:	
Durr, W. C.:	9901	Seconal Sodium capsules and	
Seconal Sodium capsules and		Benzedrine Sulfate tablets_	3303
Benzedrine Sulfate tablets	3303	Security Remedies Co.:	9909
Ebert, Carl:	5505	Security Special Udder For-	
Dr. Martin's Sulfa Du	3320	mula	3319
Electric Cord Co.:	3320	Smith, Ernest:	9919
Roll a Ray heat massage de-		diethylstilbestrol tablets and	
vice	3317	phenobarbital tablets	3308
Evans, R. J.:	9911	Stanley, W. G.:	3308
Seconal Sodium capsules, Dex-		Nurse Dencker's ointment	1 0900
		Stone, G. E.:	~ 35U 9
edrine Sulfate tablets, and	3304	Seconal Sodium capsules, dex-	
Nembutal Sodium capsules_	5504		
Evans-Drummond Drug Store.		tro-amphetamine hydrochlo-	
See Drummond, C. C., and		ride tablets, phenobarbital	
Evans, R. J.		tablets, and sulfadiazine tab-	000=
Excel Drugs:		lets	3307
pentobarbital sodium capsules,		Stone's Drug Store. See Stone,	
Seconal Sodium capsules,		G. E.	
amphetamine phosphate tab-		Surgical Dressings, Inc.:	0010
lets, and sulfadiazine tab-		surgical dressing	3312
lets	3305	Sutton, O. A., Corp.:	
Hafley, W. W.:	0004	Roll a Ray heat massage de-	
Seconal Sodium capsules	3301	vice	3317
Heinzle, F. B.:		Vitamin Industries, Inc.:	
pentobarbital sodium capsules,		Guardian vitamin A capsules,	
Seconal Sodium capsules,		Guardian D/E Plex capsules,	
amphetamine phosphate tab-		and Guardian Se-Bex tab-	
lets, and sulfadiazine tab-		lets	3314
lets	3305	Zweiback, J. L.:	
Jones Drug Co.:		Guardian vitamin A capsules,	
Seconal Sodium capsules	3301	Guardian D/E Plex capsules,	
Lenhart Drug Store. See Moore,		and Guardian Se-Bex tab-	
J. W.	,	lets	3314
1 (3309) Permanent injunction issue	đ		
1 (3309) Permanent injunction issue	L.		
11/16 7 14			

Fermanent injunction issued:

1961 - 8 YAM

000000 JAINGS THENDER AND THE AND

U. S. GOVERNMENT PRINTING OFFICE: 1951

2Nd

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3321-3340

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

Paul B. Dunbar, Commissioner of Food and Drugs. Washington, D. C., April 23, 1951.

CONTENTS*

Page	Page
Device actionable because of po-	Drugs and devices actionable be-
tential danger when used ac-	cause of false and misleading
cording to directions 300	claims 307
Drugs actionable because of failure	Drugs for human use 307
to bear adequate directions or	Drug for veterinary use 310
warning statements 300	Index 311
Drugs and devices actionable be-	
cause of deviation from official	
or own standards 306	

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3323-3325, 3327, 3328; omission of, or unsatisfactory, ingredients statements, Nos. 3323-3326; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3322-3328; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3322, 3323, 3325-3328.

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3321. Misbranding of P. M. Massager. U. S. v. Herschell R. Coil (Wawasee Therapy Co.). Plea of nolo contendere. Fine of \$100, plus costs. (F. D. C. No. 29991. Sample No. 42868–K.)

Information Filed: November 7, 1950, Northern District of Indiana, against Herschell R. Coil, trading as the Wawasee Therapy Co., Syracuse, Ind.

ALLEGED SHIPMENT: On or about November 6, 1949, from the State of Indiana into the State of Illinois.

PRODUCT: Examination showed that the device was an 8-inch hard rubber tube with a soft rubber handle on one end and a small, soft rubber lobe on the other end.

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements in circulars entitled "To Massage the Prostate through the Rectum" and "Prostate Sufferers," which accompanied the device, were false and misleading since the device would not be efficacious for the purposes represented. The statements represented and suggested that the device would be efficacious in the treatment of stiff joints, lack of ambition, tired listlessness, nervousness, aching legs, burning feet, and inability to relax due to continual tension; and that the device would be efficacious to restore virility.

Further misbranding, Section 502 (j), the device was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "a new instrument made for the sole purpose of enabling you to do this Massaging * * * It can be used gently or firmly according to the necessary requirements to remove the excess, irritating glairy liquid from the prostates * * * Five to 15 minutes twice a week gives amazing results," since such use of the device may result in perforation and rupture of the rectum, and such use by individuals with acute inflammation of the prostate may result in aggravation of the infective process.

Disposition: January 8, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$100, plus costs.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3322. Misbranding of Dexedrine Sulfate tablets and Benzedrine Sulfate tablets. U. S. v. John C. Booth (Booth Prescription Pharmacy). Plea of nolo contendere. Fine \$100 on each of first 2 counts of information; sentence suspended on remaining 2 counts. (F. D. C. No. 30012. Sample Nos. 75170-K, 75174-K, 75175-K, 75179-K.)

Information Filed: December 13, 1950, District of New Mexico, against John C. Booth, trading as the Booth Prescription Pharmacy, Portales, N. Mex.

INTERSTATE SHIPMENT: From the State of Texas into the State of New Mexico, of quantities of *Dexedrine Sulfate tablets* and *Benzedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about April 30 and May 1 and 2, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), 1 of the 3 lots of the repackaged *Dexedrine Sulfate tablets* and 1 lot of the repackaged *Benzedrine Sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

- DISPOSITION: January 2, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of the first 2 counts of the information and suspended the imposition of sentence on the remaining 2 counts.
- 3323. Misbranding of Dexedrine Sulfate tablets and phenobarbital tablets. U. S. v. Clay Blue and Carl F. Moore. Pleas of nolo contendere. Fine of \$100 against each individual on count 1; sentence suspended on remaining 3 counts of information. (F. D. C. No. 30011. Sample Nos. 49769-K to 49771-K, incl., 75177-K.)
- Information Filed: December 13, 1950, District of New Mexico, against Clay Blue and Carl F. Moore, partners in the partnership of College Drug, at Portales, N. Mex.
- INTERSTATE SHIPMENT: From the State of Texas into the State of New Mexico, of quantities of Dexedrine Sulfate tablets and phenobarbital tablets.
- ALLEGED VIOLATION: On or about May 1 and 2, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

- Disposition: January 2, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against each individual on the first count of the information and suspended the imposition of sentence on the remaining 3 counts.
- 3324. Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules. U. S. v. Asher Smith (Asher Smith Pharmacy). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 29467. Sample Nos. 60222-K, 60223-K.)
- Information Filed: November 3, 1950, Eastern District of Michigan, against Asher Smith, trading as the Asher Smith Pharmacy, Detroit, Mich.

- INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Michigan, of quantities of *Dexedrine Sulfate tablets* and *Seconal Sodium capsules*.
- ALLEGED VIOLATION: On or about January 20 and 23, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a derivative of barbituric acid, which derivative the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged Seconal Sodium capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tables* bore no label containing the common or usual name of the drug.

- DISPOSITION: January 11, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$200.
- 3325. Misbranding of Tuinal capsules, diethylstilbestrol tablets, and Sulfonamides Triplex tablets. U. S. v. John P. Taylor and Robert L. Taylor. Pleas of nolo contendere. Fine of \$400, plus costs, against each individual. (F. D. C. No. 29474. Sample Nos. 76555–K, 77358–K, 77360–K, 77382–K.)
- Information Filed: October 6, 1950, Southern District of Illinois, against John P. Taylor and Robert L. Taylor, partners in the partnership of Taylor's Drug Store, Peoria, Ill.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of Illinois, of quantities of *Tuinal capsules*, diethylstilbestrol tables, and Sulfonamides Triplex tablets.
- ALLEGED VIOLATION: On or about July 7, 12, 17, and 19, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE of CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs failed to bear labeling containing adequate directions for use since the directions "One (1) at bedtime" borne on the labeling of the repackaged *Tuinal capsules* were not adequate directions for use and the labeling of the other repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged diethylstilbestrol tablets and the Sulfonamides Triplex tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *Tuinal capsules* contained chemical derivatives of barbituric acid, which derivatives, the Federal Security

Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged diethylstilbestrol tablets bore no label containing the common or usual name of the drug; and, Section 502 (e) (2), the repackaged Sulfonamides Triplex tablets bore no label containing the common or usual name of each active ingredient of the drug.

- DISPOSITION: December 18, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$400, plus costs, against each individual.
- 3326. Misbranding of sulfathiazole tablets, thyroid tablets, diethylstilbestrol tablets, and methyltestosterone tablets. U. S. v. M & M Drugs and Max Sherman. Pleas of nolo contendere. Fine of \$200 against each defendant. (F. D. C. No. 29996. Sample Nos. 52960-K, 52964-K, 52986-K, 52999-K, 84132-K, 84338-K, 84338-K, 84333-K.)
- INFORMATION FILED: On or about November 17, 1950, Northern District of Ohio, against M & M Drugs, a partnership, Toledo, Ohio, and Max Sherman, partner and pharmacist.
- INTERSTATE SHIPMENT: From the States of New Jersey, Michigan, and Indiana, of quantities of sulfathiazole tablets, thyroid tablets, diethylstilbestrol tablets, and methyltestosterone tablets.
- ALLEGED VIOLATION: On or about January 28, February 21, and April 14, 15, 20, 24, and 25, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged thyroid tablets and diethylstilbestrol tablets and portions of the sulfathiazole tablets and methyltestosterone tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (1), the repackaged methyltestosterone tablets and a portion of the thyroid tablets bore no labels containing the common or usual name of the drugs; and, Section 502 (f) (2), the repackaged sulfathiazole tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: December 5, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$200 against each defendant.
- 3327. Misbranding of pentobarbital sodium capsules and sulfathiazole tablets. U. S. v. Morris Dunn (Dunn Drug Store). Plea of guilty. Fine of \$200 and sentence of 8 months in jail; jail sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 28108. Sample Nos. 46272-K, 46273-K, 46277-K, 46284-K.)
- Information Filed: December 6, 1949, Eastern District of Missouri, against Morris Dunn, trading as the Dunn Drug Store, St. Louis., Mo.

ALLEGED SHIPMENT: From the States of New York and Tennessee into the State of Missouri, of quantities of pentobarbital sodium capsules and sulfathiazole tablets.

ALLEGED VIOLATION: On or about May 12, 13, 22, and 26, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules and tablets to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor, or a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged *sulfathiazole* tablets bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole* tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: December 12, 1950. A plea of guilty having been entered, the court imposed a fine of \$200 and a sentence of 8 months in jail. Upon payment of the fine, the jail sentence was suspended and the defendant was placed on probation for 3 years.

3328. Misbranding of phenobarbital tablets and amphetamine sulfate tablets.
U. S. v. Tom W. Johnson. Plea of nolo contendere. Fine of \$100 on each of counts 1 and 2 of the information; sentence suspended on count 3.

(F. D. C. No. 30009. Sample Nos. 75169-K, 75171-K, 75176-K.)

Information Filed: December 13, 1950, District of New Mexico, against Tom W. Johnson, a partner in the partnership of the B & J Drug Co., Portales, N. Mex.

INTERSTATE SHIPMENT: From the States of Texas and New York into the State of New Mexico, of quantities of phenobarbital tablets and amphetamine sulfate tablets.

ALLEGED VIOLATION: On or about April 30 and May 2, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a derivative of barbituric acid, which derivative, the Federal Security Admin-

istrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: January 2, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of counts 1 and 2 of the information and suspended the imposition of sentence on count 3.

3329. Misbranding of Vit-Ra-Tox Osmotic Baths. U. S. v. 30 Cans, etc. (F. D. C. No. 30240. Sample Nos. 79696–K, 79697–K.)

LIBEL FILED: November 14, 1950, District of Massachusetts.

ALLEGED SHIPMENT: On or about September 15, 1950, from Newark, N. J.

PRODUCT: Vit-Ra-Tox Osmotic Baths. 30 cans, each containing 4½ pounds, at Franklin, Mass., and 58 cans, each containing 4½ pounds, together with a number of pamphlets entitled "I M Vit-Ra-Tox Osmotic Baths," at Boston, Mass.

RESULTS OF INVESTIGATION: The drugs had been shipped in interstate commerce at the behest of Irons & Moore, from Garden City, N. Y., in unlabeled drums, to Franklin, Mass., to be repacked into 4½-pound cans, labeled as set forth below. At the time of the investigation, 58 cans had been delivered to Irons & Moore at Boston and were accompanied by a number of the pamphlets referred to above. 30 cans were seized in possession of the repackager.

IABEL, IN PART: (Can) "I M Vit-Ra-Tox '18' Osmotic Baths National Distributors Iron & Moore, Boston, Mass. Active Ingredients Vitratox Osmotic Baths contain a new extract of the myroxylon tree from one particular tropical environment. This extract also contains eucalyptol, nerolidol and cinnamein (used as extractors) and is combined with laurel sodium sulfonate (foaming and wetting agent) and sodium carbonate (water softener). Net Weight Four Lbs. 8 Ounces \$13.95."

Nature of Charge: Misbranding, Section 502 (a), (58-can lot) certain statements in the accompanying pamphlet were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, bursitis, sciatica, sinusitis, colds, infections; infections in the bones, tissues, and muscles; tissue swellings, sore throat, rheumatic fever, asthma secondary to paranasal sinusitis, and neuritis; that the article would prevent colds and effect reabsorption of calcium deposits; and that the Food and Drug Administration had been furnished reports evidencing effectiveness of the article in relieving arthritis, bursitis, sciatica, and sinusitis, which did not recur after the lapse of months. The article would not fulfill the promises of benefit mentioned, and the Food and Drug Administration had not been furnished with the reports indicated.

Misbranding, Section 502 (f) (1), (30-can lot) the labeling failed to bear adequate directions for use since the labeling failed to indicate the diseases or conditions for which the article was intended to be used.

The article in the 30-can lot and in the 58-can lot was misbranded in the above respects while held for sale after shipment in interstate commerce.

Disposition: December 18, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3330. Adulteration of Special C. T. tablets. U. S. v. 2 Bottles, etc. (F. D. C. No. 30314. Sample No. 77391-K.)

LIBEL FILED: November 29, 1950, Southern District of Illinois.

ALLEGED SHIPMENT: On or about June 30, 1950, from St. Louis, Mo.

Product: Special C. T. tablets. 2 5,000-tablet bottles, 1 4,000-tablet bottle, 1 500-tablet bottle, and 1 250-tablet bottle, at Decatur, Ill. Examination showed that each tablet contained approximately 1/3000 grain of nitroglycerin.

Label, in Parr: "Special C. T. Tablets * * * Each C. T. contains: * * * Nitroglycerine - - - 1/200 gr."

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess since the tablets contained materially less nitroglycerin than declared on the label. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 26, 1950. Default decree of condemnation and destruction.

3331. Adulteration and misbranding of Quik-Bands. U. S. v. 10 Cases * * *. (F. D. C. No. 29495. Sample No. 47556–K.)

LIBEL FILED: July 11, 1950, Western District of Pennsylvania.

Alleged Shipment: On or about May 15, 1950, by the Seamless Rubber Co., from New Haven, Conn.

PRODUCT: 10 cases, each containing 720 tins, of Quik-Bands at Pittsburgh, Pa.

Label, IN Part: (Tin) "Rexall Firstaid Quik-Bands Adhesive Bandages With Mercurochrome * * * 36 Quik-Bands Assorted * * * Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth in the Pharmacopoeia since the gauze was not sterile.

Misbranding, Section 502 (a), the label statements (on individual bandage) "Sterile" and (on carton and tins) "Firstaid" and "Sterilized" were false and misleading.

Disposition: September 7, 1950. The Seamless Rubber Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be resterilized, under the supervision of the Food and Drug Administration.

3332. Adulteration and misbranding of prophylactics. U. S. v. 160 Gross * * * (F. D. C. No. 30321. Sample No. 81628-K.)

LIBEL FILED: December 1, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 29, 1950, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 160 gross of *prophylactics* at Philadelphia, Pa. Examination of samples showed that 2.85 percent were defective in that they contained holes.

Label, in Part: "Silver Tex."

^{*}See also No. 3340.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to the article, which contained holes: (Display carton) "Prophylactics * * * Electronically Tested * * * For Your Protection," (3-unit package) "Prophylactics * * * Electronically Tested * * * For Your Protection," (unit package) "Prophylactic," and (on article) "For Prevention Of Disease."

Disposition: January 11, 1951. Default decree of condemnation and destruction.

3333. Adulteration and misbranding of clinical thermometers. U. S. v. 26
Dozen * * * (F. D. C. No. 30146. Sample No. 58941-K.)

LIBEL FILED: November 24, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 3, 1950, by the Hygrade Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 26 dozen clinical thermometers at Chicago, Ill. Examination of 24 thermometers in accordance with specifications in C. S. 1-32 showed that 2 failed to meet the test for retreating index, 1 failed to meet the hard shaker test and entrapped gas test, and 10 had engraved markings wider than the intervening spaces.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "All Our Thermometers Are Manufactured In Accord With Their Specifications. (C. S. 1–32 Department of Commerce)" was false and misleading as applied to an article which failed to comply with the specifications stated.

DISPOSITION: January 9, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3334. Misbranding of Guardian Se-Bex tablets. U. S. v. Vitamin Stores, Inc. Plea of nolo contendere. Fine of \$125, plus costs. (F. D. C. No. 28157. Sample No. 20069–K.)

INFORMATION FILED: May 15, 1950, District of Nebraska, against Vitamin Stores, Inc., Omaha, Nebr.

Interstate Shipment: On or about August 26, 1948, from the State of Illinois into the State of Nebraska.

Alleged Violation: Between June 29 and July 13, 1949, while the *Guardian Se-Bew tablets* were being held for sale after shipment in interstate commerce, the defendant caused a placard to accompany the tablets, which act resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the placard were false and misleading since they represented and suggested that the tablets would be effective in the cure, mitigation, and treatment of hay fever, whereas the tablets would not be effective for such purposes.

^{*}See also Nos. 3321, 3329, 3331-3333.

DISPOSITION: November 24, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$125, plus costs.

3335. Misbranding of vitamin tablets. U. S. v. 197 Bottles * * *. (F. D. C. No. 29736. Sample No. 13745–K.)

LIBEL FILED: September 18, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 18, 1950, from Buffalo, N. Y.

PRODUCT: 197 bottles, each containing approximately 80 tablets, of *vitamin A & D with dicalcium phosphate* at Chambersburg, Pa., in the possession of H. Weber & Co.

RESULTS OF INVESTIGATION: This product was shipped in 5,000-tablet bottles. It was repackaged and relabeled by the consignee, H. Weber & Co., of Chambersburg, Pa.

Label, IN Part: (Bottle) "Vitamin A & D With Dicalcium Phosphate Vitamin A 3140 U. S. P. Units Viosterol 314 U. S. P. Units Dicalcium Phosphate 1 gr. One tablet taken daily contains approximately the minimum daily requirement of vitamin A & D. The equivalent of one teaspoonful Cod Liver Oil U. S. P. strength. Builds resistance to colds and disease Distributed by H. Weber & Co., Chambersburg, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Builds resistance to colds and disease" was false and misleading as applied to an article which was not effective to build resistance to colds and disease. The article was misbranded while held for sale after shipment in interstate commerce.

The product was charged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 24, 1950. Default decree of condemnation and destruction.

3336. Misbranding of Lee's iron tonic. U. S. v. 78 Bottles * * *. (F. D. C. No. 29662. Sample No. 75160–K.)

LIBEL FILED: July 27, 1950, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about May 11, 1950, by the J. J. Lee Co., from Marshall. Tex.

PRODUCT: 78 1-quart bottles of Lee's iron tonic at McComb, Miss., together with a number of leaflets entitled "The Bible Says."

LABEL, IN PART: "Lee's Iron Tonic Appetizer * * * Active Ingredients: Iron and Ammonium Citrates, Gentian Root, Thiamine Hydrochloride and a trace of Copper Sulfate (iron catalyst.)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets were false and misleading. The statements represented and suggested that the article would restore vigorous and robust health to weak, puny people; that it would prevent many serious illnesses; that it was useful in the treatment of kidney diseases, inflammation of the kidneys, Bright's disease, pyelitis, etc.; that it would make the bowels move freely; that it would nourish the muscles and give them great resilience; that it would increase muscle tone, improve digestion, and make one buoyant, robust, and healthy; that it would make one feel better, eat better, and look better; that it would build up energy; and that it would give tired, run-down, nervous,

listless folks new pep, vigor, and vim, and end that lazy sluggish feeling. The article was not capable of fulfilling the promises of benefit stated and implied.

DISPOSITION: November 7, 1950. Default decree of condemnation. Following the entry of the decree, the court ordered that the product be destroyed.

3337. Misbranding of Chase Formula. U. S. v. 7 Cases * * * (F. D. C. No. 30325. Sample No. 81874–K.)

LIBEL FILED: December 6, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about April 24, 1950, by the Chase Laboratory, from Detroit, Mich.

PRODUCT: Chase Formula. 7 cases, each containing 12 cartons and each carton containing a 2-ounce bottle, of the product at Miami, Fla. Examination disclosed that the product was a perfumed emulsion of oil and water, containing not more than 1 percent of alcohol.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in an accompanying circular entitled "A New Achievement in Laboratory Science" were false and misleading since the article was not effective in the treatment or prevention of the diseases or conditions of the body stated and implied, and contained not more than 1 percent of alcohol. The statements represented and suggested that the article contained 25 percent of denatured alcohol; that it would be effective in the treatment and prevention of impetigo, Florida sores, body lice, many types of eczema and other skin afflictions caused by external infection, muck itch, and mango poisoning; and that it would relieve the itching and burning of hives and shingles.

Disposition: January 12, 1951. Default decree of condemnation and destruction.

3338. Misbranding of Gyro-Lator reducing devices. U. S. v. 1 C. F. L. foot and leg unit, etc. (F. D. C. No. 29746. Sample Nos. 33711-K to 33718-K, incl.)

LIBEL FILED: September 26, 1950, Northern District of California.

ALLEGED SHIPMENT: On or about September 28, 1948, December 7, 12, and 19, 1949, and January 4 and February 10, 1950, by Gyrolator Division of Aciform Corp., at Chicago, Ill.

PRODUCT: 1 C. F. L. foot and leg unit, 2 Gyro Slim belts, 1 No. 6 saddle, 1 No. 9 chair, 2 Gyro Trim chairs, 3 A. T. C. treatment tables, 1 DF manual applicator for the face, and 3 DX manual applicators for the body, at Sacramento, Calif., in the possession of Gyro-ducing Salon, together with a placard entitled "Introducing The Famous Gyroducing," a booklet entitled "Gyro-ducing Method Directions For The Use of Gyrolator Units," 600 pamphlets entitled "Tip To Toe Figure Beauty," and 1,600 cards entitled "Cheer Up! Reduce! Relax!"

Each of the devices contained an electric motor connected to it so that the device would produce a vibration or oscillation.

Nature of Charge: Misbranding, Section 502 (a), the placards, booklets, pamphlets, and cards accompanying the devices contained certain statements which were false and misleading. These statements represented and suggested that the devices were effective in bringing about a reduction in weight, producing a slim figure, retaining youth, erasing lines, and producing good health

and vitality, whereas the devices were not effective for such purposes. The devices were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: October 27, 1950. Leslie D. Ray, Sacramento, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the printed matter be destroyed and that the devices be released under bond to the claimant for relabeling, under the supervision of the Food and Drug Administration.

3339. Misbranding of Hollywood Vita-Rol devices. U. S. v. 3 Devices. (F. D. C. No. 29962. Sample No. 67831–K.)

LIBEL FILED: November 1, 1950, District of Utah.

ALLEGED SHIPMENT: On or about September 15, 1950, by the S & D Engineering Co., from Glendale, Calif.

PRODUCT: 3 Hollywood Vita-Rol devices and a number of leaflets entitled "Reduce Relax Relieve" and other leaflets entitled "Hollwood Vita-Rol Instruction" at Salt Lake City, Utah. Examination disclosed that the device consisted of an electrically heated roller covered with corrugated rubber.

LABEL, IN PART: "Hollywood Vita-Rol Model A 125 Volts 76 Watts."

Nature of Charge: Misbranding, Section 502 (a), certain statements in the leaflets accompanying the device were false and misleading since the device was not effective for the purposes represented and was not an effective treatment for the conditions represented. The statements represented and suggested that the device was effective for spot reducing, and that it was effective as a body conditioner and as a treatment for muscular soreness, poor circulation, constipation, and insomnia.

DISPOSITION: February 5, 1951. Default decree of condemnation. The court ordered that the devices be delivered to the Food and Drug Administration, to be used as exhibits in connection with its work.

DRUG FOR VETERINARY USE

3340. Action to enjoin and restrain the interstate shipment of Eureka Poultry
Mixture. U. S. v. Edwin C. Singers (Eureka Poultry Food Mfg. Co.).
Consent decree granting injunction. (Inj. No. 231.)

COMPLAINT FILED: November 15, 1950, Eastern District of Illinois, against Edwin C. Singers, trading as the Eureka Poultry Food Mfg. Co., East St. Louis, Ill.

NATURE OF CHARGE: The defendant had been and was at the time of filing the complaint, introducing and delivering for introduction into interstate commerce, at East St. Louis, Ill., consignments of a drug which was labeled, in part, "Eureka Poultry Mixture Eureka Poultry Mixture is a compound composed of Red Iron Oxide and Hydrated Lime. Not less than 74% Calcium, not less than 10% Iron Oxide, not less than .5% Phosphorus."

The complaint alleged that the article was adulterated and misbranded in the following respects:

Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it contained less than 74% of calcium, less than 10% of iron oxide, and less than .5% of phosphorus.

Misbranding, Section 502 (a), certain statements in accompanying leaflets entitled "Don't Depend on Luck" were false and misleading since the article

was not effective in the prevention and treatment of the diseases and conditions stated and implied, and was not capable of fulfilling the promise of benefit and producing the results claimed. The statements represented and suggested that the article would help save little chicks and protect little chicks from gapes and worms; that it would be an effective medicine in the treatment of cholera and roup of hens; that it was a remedy and medicine for chickens; that it was effective in the prevention and treatment of white diarrhea of chicks; that it would help hens lay more eggs in winter; and that it would protect fowls from disease and keep them free from lice and mites.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the adulterated and misbranded article.

Disposition: On December 18, 1950, a temporary injunction was entered against the defendant; and on January 9, 1951, the defendant having consented to the entry of a decree, the court issued an order perpetually enjoining the defendant from introducing or delivering for introduction into interstate commerce a drug for use in the treatment of poultry and other animals which was adulterated and misbranded within the meaning of the law.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3321 TO 3340

PRODUCTS

N.	J. No.	N. J. No.
Adhesive bandages	3331	P. M. Massager 3321
Amphetamine sulfate tablets	3328	Pentobarbital sodium capsules 3327
Bandages, adhesive	3331	Phenobarbital tablets 3323, 3328
Benzedrine Sulfate tablets	3322	Prophylactics 3332
Chase Formula	3337	Quik-Bands 3331
Devices 3321, 3332, 3333, 3338,	3339	Reducing devices, Gyro-Lator 3338
Dexedrine Sulfate tablets 3322	-3324	Se-Bex tablets, Guardian 3334
Diethylstilbestrol tablets 3325	, 3326	Seconal Sodium capsules 3324
Eureka Poultry Mixture	3340	Special C. T. tablets 3330
Guardian Se-Bex tablets	3334	Sulfathiazole tablets 3326, 3327
Gyro-Lator reducing devices	3338	Sulfonamides Triplex tablets 3325
Hay fever, remedy for	3334	Thermometers, clinical 3333
Hollywood Vita-Rol devices	3339	Thyroid tablets 3326
Iron tonic, Lee's	3336	Tuinal capsules 3325
Lee's iron tonic	3336	Veterinary preparation 13340
Massager, P. M.	3321	Vitamin preparations 3334, 3335
Methyltestosterone tablets	3326	Vita-Rol devices, Hollywood 3339
Osmotic Baths, Vit-Ra-Tox	3329	Vit-Ra-Tox Osmotic Baths 3329

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N. J. No.	N. J. No.
Blue, Clay:	Booth Prescription Pharmacy.
Dexedrine Sulfate tablets and	See Booth, J. C.
phenobarbital tablets 3323	Chase Laboratory:
Booth, J. C.:	Chase Formula 3337
Dexedrine Sulfate tablets and	Coil, H. R.:
Benzedrine Sulfate tablets_ 3322	P. M. Massager 3321

^{1 (3340)} Permanent injunction issued.

N.	J. No.	N.	J. No.
Dunn, Morris:		Moore, C. F.:	
pentobarbital sodium capsules		Dexedrine Sulfate tablets and	
and sulfathiazole tablets	3327	phenobarbital tablets	33 2 3
Dunn Drug Store. See Dunn,	-	S & D Engineering Co.:	
Morris.		Hollywood Vita-Rol devices	3339
Eureka Poultry Food Mfg. Co.		Seamless Rubber Co.:	
See Singers, E. C.		Quik-Bands	3331
Gyro-ducing Salon:		Sherman, Max:	
Gyro-Lator reducing devices	3338	sulfathiazole tablets, thyroid	
Gyrolator Division of Aciform		tablets, diethylstilbestrol tab-	
Corp.:		lets, and methyltestosterone	9904
Gyro-Lator reducing devices	3338	tablets Singers, E. C.:	3326
Hygrade Thermometer Co.:		Eureka Poultry Mixture	1 22/0
clinical thermometers	3333	Smith, Asher:	9940
Irons & Moore:		Dexedrine Sulfate tablets and	
Vit-Ra-Tox Osmotic Baths	3329	Seconal Sodium capsules	3324
Johnson, T. W.:		Smith, Asher, Pharmacy, See	00=1
phenobarbital tablets and am-		Smith, Asher.	
phetamine sulfate tablets	3328	Taylor, J. P., and R. L.:	
Killashun Sales Division:		Tuinal capsules, diethylstil-	
prophylactics	3332	bestrol tablets, and Sulfona-	
Lee, J. J., Co.:		mides Triplex tablets	3325
Lee's iron tonic	333 6	Vitamin Stores, Inc.:	
M & M Drugs:		Guardian Se-Bex tablets	3334
sulfathiazole tablets, thyroid		Wawasee Therapy Co. See Coil,	
tablets, diethylstilbestrol tab-		H. R.	
lets, and methyltestosterone		Weber, H., & Co.:	
tablets	3326	vitamin tablets	3335

¹ (3340) Permanent injunction issued.

DESCRIPTION OF PARTIES.

and a control of the same of the

Y FI A FI B I LI

100- 11000

TRUTHOUSE TO THE LETTERS & D.



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

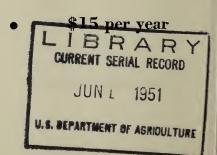
Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act] 3341-3360

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

Charles W. Crawford, Commissioner of Food and Drugs. Washington, D. C., June 11, 1951.

CONTENTS*

Page	Page
New drug shipped without effective	Devices actionable because of de-
application314	viation from official or own
Drug requiring certificate or re-	standards319
lease, for which none had been	Drugs and devices actionable be-
issued 314	cause of false and misleading
Drugs actionable because of failure	claims 320
to bear adequate directions or	Drugs for human use 320
warning statements 315	Drug for veterinary use 327
Drugs actionable because of con-	Index 327
tamination with filth 318	021

^{*}For omission of, or unsatisfactory, ingredients statements, see Nos. 3347, 3353; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3343, 3353; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3353; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3352.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3341. TB-One tablets. U. S. v. 2 Cases * * * (F. D. C. No. 29786. Sample No. 86304-K.)

LIBEL FILED: October 5, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about September 13, 1950, by the Cosmos Chemical Corp., from New York, N. Y.

PRODUCT: 2 cases, each containing 44 boxes and each box containing 12 50-tablet bottles, of TB-One tablets at Los Angeles, Calif.

RESULTS OF INVESTIGATION: This drug was a new drug within the meaning of Section 201 (p) (1) of the law since the name "TB-One," together with the label statement "Caution: To be used only by or on the prescription of a physician," suggested that it was for use in the treatment of tuberculosis in the dosage which had been recommended for the disease in published reports by some physicians, namely 2 to 8 tablets per day for six months or longer; and it was not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under these conditions.

LABEL, IN PART: (Bottle) "TB-One Para Acetylaminobenzal Thiosemicarbazone 25 Mg. Caution: To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: November 27, 1950. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3342. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 33 Cartons * * * (F. D. C. No. 30261. Sample No. 93094-K.)

LIBEL FILED: November 30, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about September 20, 1950, by the Brookfield Laboratories, from Chicago, Ill.

PRODUCT: 33 retail cartons, each containing 1 tube, of Dr. Merrick's Ear Canker Creme at Tampa, Fla.

LABEL, IN PART: (Retail carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin, Tyrothricin, 2 Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate * * * Net Contents ½ Ounce."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since it contained but an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which contained but an inconsequential trace, if any, of aureomycin: (Display carton) "contains * * * Aureomycin," (retail carton) "Active Ingredients: Aureomycin," and (leaflet in retail carton) "Aureomycin and Tyrothricin

* * By combining the two antibiotics we obtain a very desirable synergistic action resulting in more effective curative action than when either Aureomycin or Tyrothricin is used separately."

Further misbranding, Section 502 (1), the article purported to be and was represented as a drug composed in whole or in part of aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: January 9, 1951. Default of decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3343. Misbranding of methyltestosterone tablets. U. S. v. Zeno M. Weir (Weir's Drugs & Jewelry). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 29433. Sample Nos. 51383-K, 51388-K, 52645-K.)
- Information Filed: August 30, 1950, Western District of Kentucky, against Zeno M. Weir, trading as Weir's Drugs & Jewelry, Owensboro, Ky.
- INTERSTATE SHIPMENT: From the State of New Jersey into the State of Kentucky, of quantities of methyltestosterone tablets.
- ALLEGED VIOLATION: On or about November 1, 14, and 16, 1949, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a physician's prescription, which acts resulted in the tablets being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged tablets bore no labeling containing directions for use.
- Disposition: February 13, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$150.
- 3344. Misbranding of Nue-Ovo. U. S. v. 24 Units * * * (and 13 other seizure actions.) (F. D. C. Nos. 24663, 24672, 24972, 25050, 25243, 25259, 25272, 25420, 25504, 25516, 26466, 26506, 26538, 26564, 26854. Sample Nos. 7987-K, 12576-K, 15579-K, 20629-K, 21902-K, 21904-K, 27531-K, 28984-K, 28985-K, 31372-K, 31374-K, 40639-K, 40683-K, 40690-K.)
- LIBELS FILED: Between June 3, 1948, and April 1, 1949, District of Utah, Western District of Missouri, Southern District of California, Northern District of Oklahoma, District of Kansas, Western District of Washington, Eastern District of Michigan, and Middle and Western Districts of Pennsylvania.
- ALLEGED SHIPMENT: Between January 11, 1947, and February 15, 1949, by the Nue-Ovo Co., from Chicago, Ill., and by Research Laboratories, Inc., from Portland, Oreg.
- PRODUCT: Nue-Ovo. 41 1-pint bottles; 147 units, each containing 3 1-pint bottles; and 8 cases, each containing 6 units of 3 1-pint bottles, at Salt Lake City and Ogden, Utah; Springfield, Mo.; Glendale and Vernon, Calif.; Miami, Okla.; Hutchinson and Lawrence, Kans.; Bellefonte and Pittsburgh, Pa.; Tacoma, Raymond, and Olympia, Wash.; and Detroit, Mich.

LABEL, IN PART: (Bottle) "Nue-Ovo * * * Active Ingredients: An Aqueous Extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B₁."

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements on the display cards and circulars accompanying one of the Kansas lots were false and misleading since such statements represented and suggested that the article was effective in the treatment of arthritis and rheumatism, whereas it would not be effective for such purposes.

Misbranding, Section 502 (f) (1), the labeling of the article in the other lots failed to bear adequate directions for use since it failed to reveal the diseases or conditions of the body for which the article, when used as directed, would be effective.

DISPOSITION: Research Laboratories, Inc., appeared as claimant for all lots, with the exception of that seized at Olympia, Wash. On motion of the claimant, the actions instituted at Salt Lake City and Ogden, Utah, Pittsburgh, Pa., Springfield, Mo., and Glendale and Vernon, Calif., were removed for trial and final disposition to the Northern District of Illinois; and stipulations were entered in the other cases involving Section 502 (f) (1) charges, that the actions would wait the result and be governed by the judgment in the consolidated case.

On October 27, 1950, by consent of the claimant, judgment was entered in the Northern District of Illinois in the consolidated case, condemning the product and ordering that it be destroyed. The other actions involving Section 502 (f) (1) charges, were terminated on various dates between December 28, 1950, and February 5, 1951, by the entry of similar decrees.

The seizure at Lawrence, Kans., involving Section 502 (a) charges, was terminated on February 21, 1950, by the entry of a decree of condemnation and destruction, in accordance with a stipulation entered into that the disposition of the product would be governed by the judgment entered in the consolidated action reported in notices of judgment on drugs and devices, No. 2963.

On January 16, 1951, a default decree of condemnation was entered in the case instituted at Olympia, Wash., and the court ordered that the product be destroyed.

3345. Misbranding of Nue-Ovo. U. S. v. 4 Units * * * * (F. D. C. No. 25171. Sample No. 28565-K.)

LIBEL FILED: July 16, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about April 7, 1948, from Chicago, Ill.

Product: 4 units, each containing 3 1-pint bottles, of Nue-Ovo at Denver, Colo.

NATURE of CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the diseases or conditions of the body for which the article, when used as directed, would be effective. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 27, 1950. Research Laboratories, Inc, claimant, having consented to the entry of a decree and the case having been consolidated with certain other cases referred to in the preceding notice of judgment in the

Northern District of Illinois (No. 3344), judgment of condemnation was entered and the court ordered that the product be destroyed.

3346. Misbranding of Weber's laxative cold tablets. U. S. v. 97 Bottles * * *. (F. D. C. No. 29701. Sample No. 13746-K.)

LIBEL FILED: August 28, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 9, 1950, from Buffalo, N. Y.

PRODUCT: 97 bottles of Weber's laxative cold tablets at Chambersburg, Pa., in possession of H. Weber & Co.

RESULTS OF INVESTIGATION: Investigation disclosed that the tablets were repacked after completion of the interstate shipment.

Label, in Part: "Weber's Laxative Cold Tablets For Colds and LaGrippe * * * Each Tablet Represents Acetanilid 2 gr. Tincture Aconite 3½ M Tincture Gelsemium 4½ M Ipecac ½ gr. Aloin ½0 gr. Podophyllin ½0 gr. Capsicum ½ gr."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For Colds and LaGrippe" was false and misleading since the article would not be effective in the treatment of such conditions; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users since the label failed to warn that the frequent or continued use of an article containing acetanilid may be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug; and the label failed also to warn that frequent or continued use of the article may result in a dependence on laxatives, and that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 5, 1951. Default decree of condemnation and destruction.

Misbranding of Rheumolek Herb Tea No. 3 and Hematone Herb Tea No.
 U. S. v. 15 Bags, etc. (F. D. C. No. 30359. Sample Nos. 81768-K to 81771-K, incl.)

LIBEL FILED: December 28, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 28, October 6, and November 8, 1950, from New York, N. Y., by E. C. Diez Drug Co., Inc.

PRODUCT: 15 bags and 150 cartons of Rheumolek Herb Tea No. 3, and 8 bags and 100 cartons of Hematone Herb Tea No. 4, at Morrisville, Pa., in possession of Tatra Co., together with a number of order blanks headed "Odtrhnete A Poslete Tuto Objednavku Na Adresu."

RESULTS OF INVESTIGATION: The products were shipped in 100-pound bags to which were attached tags bearing the names and addresses of the shipper and consignee on one side and on the reverse side the statement "100 #3" or "100 #4."

The consignee had repackaged portions of the contents of the bags in cartons holding 5 ounces each, and had labeled the cartons as set forth below.

LABEL, IN PART: (Carton) "Rheumolek Herb Tea No. 3 * * * Buchu Leaves, Black Cohosh, Pipsissewa, Wintergreen, Bearberry, Coriander, Rosemary Leaves, Fennel, Senna Pods, Elder Flowers, Nettle Leaves, Licorice, Marshmallow Root" and "Hematone Herb Tea No. 4 * * * Sarsaparilla Root, Burdock Root, Peppermint, Anise, Licorice, Yarrow Herb, Senna, Safflowers, Fennel, Yellow Dock Root."

NATURE OF CHARGE: The products were misbranded when introduced into, and while in, interstate commerce as follows: Section 502 (e), the labels of the articles failed to bear the names of the active ingredients contained therein; and, Section 502 (f) (1), the labeling failed to bear adequate directions for use since it bore no directions for use.

The products were misbranded, Section 502 (a), while held for sale after shipment in interstate commerce. The following statements on the labels and on the accompanying order blanks were false and misleading: (Carton) "Rheumolek * * * A compound of medicinally proven herbs as an aid in relieving the pains of Rheumatism, Neuritis, Arthritis, Neuralgia, Sciatica and Lumbago, by promoting elimination of excess acids and wastes, when due to sluggish action of the kidneys. Diuretic Alterative Sedative * * * Assists the organs of elimination; removes waste and poisonous matter and reduces excess acidity" and (order blank in Slovak) "Rheumolek Are you worried about rheumatic pains in your arms, legs, or back? Do you have pains in your bones? Why suffer longer! The wonderful 'Rheumolek' Tea #3 can help you * * * relief * * * you will get from this * * * Tea"; (carton) "Hematone * * * blend of herbs especially recommended * * * for * * * Tonic and Alterative properties, when indicated in certain conditions of poor blood, sallow complexion and skin eruptions, resulting from excessive waste in the system due to faulty elimination. Aids in Purifying * * * Vitalizing and Enriching the Blood" and (order blank in Slovak) "Our 'Hematone Blood Tea #4' * * * for cleaning and enriching your blood, if you want pure healthy blood, to rid yourself of any unpleasantness of feeling, to have a beautiful skin, regain your normal strength and have a feeling of well being * * * you must have pure blood." The products would not be effective for the purposes stated and implied, and would not fulfill the promises of benefit made for them in the above statements.

DISPOSITION: January 11, 1951. The Tatra Co., Morrisville, Pa., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond to be relabeled, under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3348. Adulteration of orrisroot and chamomile flowers. U. S. v. 12 Bags, etc. (F. D. C. No. 29840. Sample Nos. 73039-K, 73040-K.)

LIBEL FILED: October 20, 1950, Southern District of New York.

ALLEGED SHIPMENT: The *orrisroot* was imported from Italy prior to March 23, 1949, and the *chamomile flowers* were imported from Belgium on or about November 9, 1949.

PRODUCT: 12 bags, each containing 160 pounds, of *orrisroot*, and 12 bags, each containing 110 pounds of *chamomile flowers*, at New York, N Y.

Nature of Charge: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of insects. The articles were adulterated while held for sale after shipment in interstate commerce.

Disposition: November 16, 1950. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruction of 187 pounds of orrisroot and 372 pounds of chamomile flowers.

DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3349. Adulteration and misbranding of clinical thermometers. U. S. v. 25 Cartons * * *. (F. D. C. No. 30238. Sample No. 85788-K.)

LIBEL FILED: November 13, 1950, Southern District of Texas.

ALLEGED SHIPMENT: On or about October 4, 1950, by the Arvesen Thermometer Corp., from Brooklyn, N. Y.

PRODUCT: 25 cartons each containing 2 dozen clinical thermometers at Galveston, Tex. Examination of 23 thermometers showed that 2 failed to meet the requirement in the United States Department of Commerce Standard C. S. 1–42 for clinical thermometers for accuracy of readings, and that 13 additional thermometers failed to meet the test for entrapped gas, required by the above standard.

LABEL, IN PART: (Carton) "Fahrenheit Clinical Thermometers."

Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess, namely, "Clinical Thermometers."

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article did not comply with the United States Department of Commerce Standard C. S. 1–42 for clinical thermometers: "We, the undersigned Manufacturers, hereby certify that our registering clinical thermometer marked No. has been examined and tested and found to meet all the requirements and tests specified in the United States Department of Commerce, Commercial Standard C. S. 1–42 for Clinical Thermometers * * *."

DISPOSITION: December 20, 1950. Default decree of condemnation and destruction.

3350. Adulteration and misbranding of clinical thermometers. U. S. v. 4 Gross

* * * (F. D. C. No. 30239. Sample No. 81877-K.)

Libel Filed: November 10, 1950, Southern District of Florida.

Alleged Shipment: On or about October 13, 1950, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 4 gross of *clinical thermometers* at Miami, Fla Examination of 24 thermometers showed that 6 failed to give readings of the claimed accuracy; that 1 was a retreater; and that 1 failed to meet the hard shaker test. The normal temperature arrow on 1 thermometer pointed to the 99° mark.

LABEL, IN PART: "Cardinal Oral."

NATURE of CHARGE: Adulteration, section 501 (c), the quality of the article fell below that which it purported and was represented to possess, namely, "Clinical Thermometer" and "correct within plus or minus 2/10 F." at 98°, 102°, and 106°.

^{*}See also No. 3342.

Misbranding, Section 502 (a), the normal temperature arrow pointing to the 99° mark was misleading since it should point to the 98.6° mark; and the following statements in the labeling of the article were false and misleading as applied to the article, which would not give accurate readings: "This certifies that the enclosed thermometers have been tested on the above date at 98°, 102°, and 106° F. and are correct within plus or minus 2/10 F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–32 Department of Commerce). The enclosed thermometers are guaranteed to be of absolute accuracy."

DISPOSITION: January 12, 1951 Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3351. Misbranding of To-Ne-Ka herbs, Black Eagle medicine, and Toneka tonic tablets. U. S. v. 27 Packages, etc. (F. D. C. No. 30366. Sample Nos. 43385-K to 43388-K, incl.)

LIBEL FILED: January 24, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 5 and October 13 and 16, 1950, from Cincinnati, Ohio.

Product: 27 2-ounce packages and 29 1-ounce packages of To-Ne-Ka herbs, 23 8-ounce bottles of Black Eagle medicine, and 31 30-tablet packages of Toneka tonic tablets at Chicago, Ill., in possession of George H. Davis, together with a number of leaflets entitled "Nature's Way To Health and Relief," "To Get Back To Daily Habit Time," and "When You Feel The Symptoms."

RESULTS OF INVESTIGATION: The leaflets were designed by Mr. Davis and were printed upon his instructions. They were sent to prospective customers and were distributed with each article sold.

LABEL, IN PART: (Package) "To-Ne-Ka Brand Herbs * * * Active Laxative Ingredients: Buckthorn, Aloe and Senna Leaves. Active Stomachic and Stimulant to the Appetite Ingredients: Gentian, Ginger, Calamus, Quassia and Burdock Root"; (bottle) "Black Eagle Brand Medicine * * * Active Laxative Ingredients: Sodium Phosphate, Senna, Cascara Sagrada and Buckthorn. Active Carminative Ingredients: Cinnamic Aldehyde, Fennel, Ginger, Oil Peppermint and Oil Cassia"; and (package) "Toneka Brand Tonic Tablets * * * Active Ingredients: Iron (Ferrous) Sulphate, and Gentian Root."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the leaflets were false and misleading since the articles were not capable of fulfilling the promises of benefits, stated and implied: (To-Ne-Ka Herbs) "Good Health * * * When the intestines are not functioning properly, the residue remains in the large intestines, distends them and weakens their muscles, fermenting waste matter may accumulate and release poisonous gases. Old Folks and young folks, too, who are troubled with biliousness * * * sick, sour stomach, belching, bloating, gas on stomach, poor ap-

^{*}See also Nos. 3342, 3344, 3346, 3347, 3349, 3350.

petite, bad breath, sick headache, dizziness, sensation of fullness after meals, uneasiness, depression of spirits, etc., may find relief with the use of: To-Ne-ka (Herbs * * * for the relief from ills of mankind * * * If you seem to lack the pep and go that you used to have, if your liver seems sluggish and your legs feel crampy * * * Try To-Ne-Ka Herbs"; (Black Eagle medicine) "To have normal elimination instead of the harsh laxative way, use this gentle but positive liquid herb medicine that encourages daily, regular elimination * * * When you are tired and feel worn out, troubled with biliousness * * * sick, sour stomach, gas on stomach, poor appetite, fullness after meals * * * Enjoy New Life * * * You may be free of all * * * bad breath, sick headaches, dizziness, depression of spirits; you may enjoy a feeling of new life—have pep and go * * * When your liver seems sluggish and your legs feel crampy—you may find relief in the use of Black Eagle Brand Medicine * * * A Liquid Herb Medicine that is easy and pleasant to take. Contains nothing harmful and may be taken by children as well as adults with assurance of safety"; and (Toneka tonic tablets) "When there is Lack of Zip and Zest, and you otherwise Don't Feel up to par * * * When you feel nervous, dull, lazy, and have no ambition to work or play * * * feel blue, when headaches get the best of you and you feel old before your time, and life seems to be not worth living * * * Toneka Iron Tonic may then be what you need * * * Nature's minerals and roots, the oldest and most reliable remedy for rheumatism, kidney and stomach ailments. Watch your elimination from your bowels a day or two after using it. The waste, black as the color of your shoes, will start to break away * * * Also examine your urine. You may see poisonous wastes and impurities coming from your kidneys, relieving you * * * Try Toneka Iron Tonic Tablets Regardless of how long you have been suffering." The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 14, 1951. Default decree of condemnation and destruction.

3352. Misbranding of Yerbama. U. S. v. 100 Packages, etc. (F. D. C. No. 30335. Sample No. 80139–K.)

Libel Filed: December 11, 1950, District of Massachusetts.

ALLEGED SHIPMENT: From the Country of Brazil.

PRODUCT: 100 8-ounce packages of Yerbama at Boston, Mass., in possession of the BrazilianYerbama Co., together with a quantity of the product in bulk, a number of booklets entitled "Health," and a number of leaflets entitled "Yerbama."

RESULTS OF INVESTIGATION: The article was imported from Brazil in bulk, and a portion was repackaged and relabeled by the dealer. The booklets and the leaflets were printed locally for the dealer.

LABEL, IN PART: (Package) "Yerbama * * * Contents: 100% Dried Leaves Ilex Paraguayensis."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements, which appeared on the package label and in the booklets and leaflets, were false and misleading since the action of the article on the user differed from that stated and implied: (Carton label) "Nutritious and bracing for nerve and muscle Does not cause insomnia or disturbance of heart action * * * a nutritious and mentally invigorating food beverage. It stimulates the func-

tions of the brain and muscles * * * Yerbama is a first class stimulant for the muscles, nerves and brains * * * without affecting the heart or disturbing the sleep. It is less of an excitant than tea or coffee and * * * does not cause insomnia, neither does it cause pertubations of the heart * * * there is no harmful physical reaction or mental disturbance." (Booklet entitled "Health") "Health * * * Out-Of-Repair Must Not Be Asked To Wait Good Health! From the U.S. of Brazil * * * a nutritious and mentally invigorating food-beverage. The millions in South America who consume it daily * * * live long to rejoice in it. The State of Parana is famed for its high percentage of centenarians. Yerbama * * * from the sunny plantations of Parana * * * It acts as a restorative after great fatigue * * * a fortifier against severe mental or physical work"; and (leaflet entitled "Yerbama") "* * * Nutritious & Bracing For Nerve & Muscle Does Not Cause Insomnia Or Disturbance Of Heart Action."

Further misbranding, Section 502 (c), the information required by law to appear on the label, namely, the common or usual name of the article, maté, was not prominently displayed on the label with such conspicuousness (as compared with the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 22, 1951. Default decree of condemnation and destruction.

3353. Misbranding of Alfanol. U. S. v. 9 Cartons * * *. (F. D. C. No. Sample No. 78852-K.) 30129.

Libel Filed: November 17, 1950, Northern District of California.

ALLEGED SHIPMENT: On or about September 11, 1950, by the Alfanol Co., from Shedd, Oreg.

PRODUCT: 9 unlabeled cartons each containing 1 bottle of Alfanol and a circular entitled "Alfanol" at Eureka, Calif. Examination showed that the product consisted essentially of sodium polysulfide, sodium sulfate, and sodium thiosulfate, dissolved in water.

LABEL, IN PART: (Bottle) "Two Fluid Ounces Alfanol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the circular, which represented and suggested that the article was effective in relieving the pains of arthritis and rheumatism, were false and misleading since the article would not be effective for such purposes; Sections 502 (b) (1) and (2), the carton label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and Section 502 (e) (2), the article was fabricated from two or more ingredients, and the carton label failed to bear the common or usual name of each active ingredient.

DISPOSITION: December 13, 1950. Default decree of condemnation and destruction.

3354. Misbranding of Muscle-Rub. U. S. v. 79 Bottles, etc. (F. D. C. No. 28539. Sample No. 75425-K.)

LIBEL FILED: January 23, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about October 17 and December 6, 1949, by Muscle-Rub Distributors, from Los Angeles, Calif.

PRODUCT: Muscle-Rub. 79 2-ounce bottles, 28 6-ounce bottles, and 24 12-ounce bottles at Denver, Colo., together with a leaflet attached to each bottle entitled "Muscle-Rub" and one clipping from the January 9, 1950, edition of The Denver Post.

RESULTS OF INVESTIGATION: The newspaper clipping was on display in the store of the consignee.

Label, in Part: (Bottle) "Muscle-Rub Contains Isopropyl Alcohol 75% Ethyl Alcohol 1.8% Methyl Salicylate, Camphor, Menthol and Fld. Ext. Witch Hazel."

NATURE OF CHARGE: Misbranding, Section 502 (a) the following statements on the bottle labels and in the leaflets were false and misleading since the article was not effective in the treatment of the conditions stated and implied: (Bottle) "Use as an aid in the Relief of Pain and Discomfort from Rheumatism, Arthritis, Neuralgia, Sciatica" and (leaflet) "Glorious Aid in the Relief of Pain and Discomfort from Rheumatism, Arthritis, Neuralgia, Sciatica." The article was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the following statements in the newspaper clipping were false and misleading since the article was not effective in the treatment of the conditions stated and implied: "to quickly relieve the pains of Rheumatism, Arthritis, Neuritis, Lumbago, Sore Lame Muscles Why suffer another day from the agony of these painful ailments? Prove free that you can get miraculous relief in just a few minutes from rheumatic pains, muscle soreness, sprains, as well as serious lameness of muscles and joints. * * * The entire Muscle-Rub treatment is a penetrating, blood-stimulating liquid applied directly to the limbs, shoulders, neck, face or back-wherever you are suffering pain. You get action right away. Pain is usually relieved in just a few minutes * * * Rheumatism Pains Relieved in Few Minutes * * * quick relief from agonizing pains. 50-Year-Old Los Angeles Lady Says Muscle-Rub is Godsend. 'I've had rheumatism many years and have suffered awfully from sharp pains. Sometimes I couldn't move. I hurt so. Six years ago I discovered Muscle-Rub and got blessed relief at last.' 'Thank God for Muscle Rub,' says California Rheumatic Sufferer. 'I read your ad and bought Muscle-Rub. I have tried everything I could buy but could not raise my right arm until I used Muscle-Rub. I am a carpenter so you see how I suffered. Thank God I found Muscle-Rub and got relief. I feel fine, working every day and I am 61 years old."

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

Disposition: January 16, 1951. The libel proceedings having been removed for trial to the Northern District of California, and the claimant, Muscle-Rub Distributors, having failed to file an answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

3355. Misbranding of Ipsab Gum Massage. U. S. v. 3 Bottles, etc. (F. D. C. No. 30248. Sample No. 11029-K.)

LIBEL FILED: November 13, 1950, Southern District of New York.

ALLEGED SHIPMENT: During 1948 and 1949, from Norfolk, Va.

PRODUCT: 3 1-gallon bottles and 17 cartons, each carton containing 1 1-ounce bottle, of *Ipsab Gum Massage* at New York, N. Y., in possession of Ipsab Distributors.

RESULTS OF INVESTIGATION: The article in the cartons was repackaged and labeled by the consignee after it had been originally shipped in gallon bottles as described above. A circular entitled "Your Mouth" was included in each 1-ounce carton. The consignee also had on hand an additional number of the circulars and a number of bottle and carton labels.

LABEL, IN PART: (Carton) "Original Formula Ipsab gum massage * * * Ingredients: Atomic Iodine, Calcium Chloride, Sodium Chloride, Prickly Ash Bark, Essence of Peppermint."

Nature of Charge: Misbranding, Section 502 (a), the labeling of the article in the bottles and in the cartons contained false and misleading statements. The statements represented and suggested that the article was an adequate and effective treatment for sore, tender, bleeding, and spongy gums, gingivitis, pyorrhea, ulcerations of the mouth, gum boils, canker sores, loose teeth, and receding gums, and that it would increase circulation, strengthen tissues, and keep gums in healthy condition. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit stated and implied. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 18, 1951. Default decree of condemnation and destruction.

3356. Misbranding of hair and scalp oil. U. S. v. 24 Dozen Jars, etc. (F. D. C. No. 30455. Sample No. 85101–K.)

LIBEL FILED: December 28, 1950, Southern District of Ohio.

Alleged Shipment: On or about July 24, 1950, from Camden, N. J.

PRODUCT: 24 dozen 1½ ounce jars of hair and scalp oil at Cincinnati, Ohio, in the possession of the Avenue Beauty Shoppe, together with a number of labels reading "Gro-Aid Hair and Scalp Oil 1½ ounces Distributors Parrish Products Company, 608 W. Fifth Street, Cincinnati 3, Ohio." A portion of the jars were labeled with the above label.

RESULTS OF INVESTIGATION: This product was shipped unlabeled, but a portion was labeled by the consignee, the Avenue Beauty Shoppe, after shipment. Analysis showed that the product consisted essentially of petrolatum and methyl salicylate.

Nature of Charge: Misbranding, Section 502 (a), the label designation "Gro-Aid Hair and Scalp Oil" was false and misleading since the article would not be effective in promoting the growth of hair. The product was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 29, 1951. The Avenue Beauty Shoppe, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond to be relabeled, under the supervision of the Food and Drug Administration.

3357. Misbranding of Electreat (device). U. S. v. Charles Willie Kent (Electreat Mfg. Co.). Plea of not guilty. Tried to the court and jury. Verdict of guilty. Fine of \$1,000, plus costs. (F. D. C. No. 23270. Sample No. 49770-H.)

INFORMATION FILED: December 23, 1947, Southern District of Illinois, against Charles Willie Kent, trading as the Electreat Mfg. Co., Peoria, Ill.

ALLEGED SHIPMENT: On or about March 17, 1947, from the State of Illinois into the State of Texas.

Nature of Charge: Misbranding, Section 502 (a), the labeling of the device, including accompanying circulars entitled "Electreat Instruction Chart" and "Do You Want to Improve Your Health?" contained false and misleading statements. The statements represented and suggested that the device would improve health; that it would relieve muscular aches and pains; that it would be efficacious in the cure, mitigation, treatment, and prevention of sinus trouble, arthritis, earaches, menstrual disturbances, sleeplessness, nervous disorders, rheumatism, heart attack, and paralysis; and that it would remove dandruff. The device would not improve health; it would not relieve muscular aches and pains; it would not be efficacious in the cure, mitigation, treatment, and prevention of sinus trouble, arthritis, earaches, menstrual disturbances, sleeplessness, nervous disorders, rheumatism, heart attack, and paralysis; and it would not remove dandruff.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court and jury on September 11, 1950. The trial was concluded on September 21, 1950, at which time the jury returned a verdict of guilty. Thereafter, motions for arrest of judgment and for a new trial were filed on behalf of the defendant; and on January 24, 1951, after consideration of the arguments of counsel, the court denied the motions and imposed a fine of \$1,000, plus costs, against the defendant.

3358. Misbranding of Enderlins Electrolytic Health Compress (device). U. S. v. 99 Unlabeled Devices * * * (F. D. C. No. 29771. Sample No. 35565-K.)

LIBEL FILED: October 3, 1950, Northern District of California.

ALLEGED SHIPMENT: On or about December 29, 1949, from Munich, Germany,

PRODUCT: 99 unlabeled devices at San Francisco, Calif., together with leaflets entitled "Enderlins Electrolytic Health Compress," in possession of Dr. Herbert O. Weber.

The device consisted of a plastic box attached to a cotton strap or belt. Terminals of a flashlight battery inside the box were connected to 2 round metal disks on the outside. The device was to be strapped on the body, with the 2 disks in contact with the skin.

NATURE OF CHARGE: Certain false and misleading statements in the leaflets misbranded the devices, Section 502 (a), while they were held for sale after shipment in interstate commerce. These statements represented and suggested that the device would act by way of the blood stream and nervous system upon the entire organism; that it would change part of the body acids into

electromagnetic energy and create an intensification of "life force radiation"; that it would increase the activity of the central nervous system, activate the functions of the glands, normalize the circulation, dissolve foreign bodies, and accelerate their elimination; and that when the device was used as a supplement to regular treatment by a physician, it would be helpful as a relief and could speed and assure complete health in the following conditions: signs of old age, asthma, chronic conditions of joints, arteriosclerosis, diseases of the heart, gout, atrophy of muscles, weakness of nerves, kidney diseases, sleeplessness and conditions due to it, high blood pressure, sciatica, cramps, disturbances of circulation, paralysis caused by stroke, disturbances in liver and gall bladder, paralysis of nerves, neuralgia, rheumatic conditions, and metabolic disturbances. The device when used as directed, was not effective in the treatment of such diseases and conditions.

DISPOSITION: October 18, 1950. Default decree of condemnation and destruction.

3359. Misbranding of California Dri-Aire Lamp. U. S. v. 11 Devices, etc. (F. D. C. No. 30347. Sample No. 78574-K.)

LIBEL FILED: January 4, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about March 10, April 4, and May 11, 1950, and on an unknown date prior to March 10, 1950, by Abbey Rents, from Los Angeles, Calif.

PRODUCT: 11 devices known as California Dri-Aire Lamp at Seattle, Wash., in possession of Abbey Rents, together with an accompanying display card entitled "The California Dri-Aire Lamp" and accompanying leaflets entitled "Desert Air Indoors."

Examination showed that the device consisted of a ceramic core heating element and metal reflector mounted on a stand which was adjustable as to height.

RESULTS OF INVESTIGATION: The display card was received 2 or more years before, from Abbey Rents, Portland, Oreg., or Los Angeles, Calif., and the leaflets were received from Abbey Rents, Los Angeles, Calif., sometime since September 1949. The display card was on display in the window of the consignee's place of business, and the leaflets were handed to potential customers.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the device and display card and in the leaflets were false and misleading. These statements represented and suggested that the device was an adequate and effective treatment for respiratory and circulatory ailments, colds, throat irritations, asthma, sinusitis, bronchitis, hay fever, childs' coughs, colds, croup, whooping cough, or other breathing trouble, arthritis, bursitis, neuritis, aching muscles, rheumatic conditions, sacroiliac pain, neuralgia, tuberculosis, and weakening conditions; and that the device would promote health, impede the action of germs in the respiratory tract, clear respiratory passages for easier breathing, and remove moisture from the air. The device would not be an adequate and effective treatment for the conditions represented.

The devices were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 22, 1951. Abbey Rents, Los Angeles, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUG FOR VETERINARY USE

3360. Misbranding of Chic-Tone Co.'s inhalant for poultry. U. S. v. 14

Jugs * * * (F. D. C. No. 30247. Sample No. 40367-K.)

LIBEL FILED: November 10, 1950, District of Maryland.

ALLEGED SHIPMENT: On or about September 6, 1950, by the Chic-Tone Co., from York, Pa.

PRODUCT: 14 1-gallon jugs of Chic-Tone Co.'s inhalant for poultry at Preston, Md.

Label, IN Part: "Percentage Composition By Volume Active Ingredients: Formaldehyde 7% (Equivalent to 17.50% U. S. P. Liquor Formaldehyde). Expectorant Oil (Oil of Eucalyptus U. S. P.) 1.17%. Boric Acid U. S. P. 0.78%. Ethyl Alcohol 7.89%. Inert material to make 100%."

NATURE of CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective for the purposes stated and implied: "An Alleviant For Colds, Bronchitis, & Upper Respiratory Diseases Exciting a stimulating expectorant action to assist the birds in expelling accumulations of mucus from the upper respiratory tract."

Disposition: December 18, 1950. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3341 TO 3360 PRODUCTS

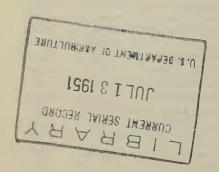
N. J. No.	N. J. No.
Alfanol 3353	Ipsab Gum Massage 3355
Arthritis, remedies for 3344,	Laxative without required warn-
3347, 3353, 3354	ing statements 3346
Black Eagle medicine 3351	Liniment 3354
California Dri-Aire Lamp 3359	Merrick's, Dr., Ear Canker
Chamomile flowers 3348	Creme 3342
Chic-Tone Co.'s inhalant for poul-	Methyltestosterone tablets 3343
try 3360	Muscle-Rub 3354
Colds, remedy for 3346	Nue-Ovo 3344, 3345
Dental preparation 3355	Oil, hair and scalp 3356
Devices 3349, 3350, 13357-3359	Ointment 3356
Dri-Aire Lamp, California 3359	Orrisroot 3348
Ear Canker Creme, Dr. Mer-	Rheumatism, remedies for 3344,
rick's 3342	3347, 3353, 3354
Electreat (device) 13357	Rheumolek Herb Tea No. 3 3347
Electrolytic Health Compress	TB-One tablets 3341
(device), Enderlins 3358	Thermometers, clinical 3349, 3350
Enderlins Electrolytic Health	To-Ne-Ka herbs 3351
Compress (device) 3358	
Gum Massage, Ipsab 3355	
Hair and scalp preparation 3356	Tuberculosis, remedy for 3341
Hematone Herb Tea No. 4 3347	Veterinary preparation 3360
Inhalant for poultry, Chic-Tone	Weber's laxative cold tablets 3346
Co.'s 3360	Yerbama 3352

^{1 (3357)} Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N	. J. No.	N. J. No.
Abbey Rents:		Electreat Mfg. Co. See Kent,
California Dri-Aire Lan-p	3359	C. W.
Alfanol Co.:		Ipsab Distributors:
Alfanol	3353	Ipsab Gum Massage 3355
Arvesen Thermometer Corp.:		Kent, C. W.:
clinical thermometers	3349	Electreat (device) 13357
Avenue Beauty Shoppe:		Muscle-Rub Distributors:
hair and scalp oil	3356	Muscle-Rub 3354
Brazilian Yerbama Co.:		Nue-Ovo Co.:
Yerbama	3352	Nue-Ovo 3344
Brookfield Laboratories:		Parrish Products Co.:
Dr. Merrick's Ear Canker		hair and scalp oil 3356
Creme	3342	Research Laboratories, Inc.:
Cardinal Thermometer Co.:		Nue-Ovo 3344
clinical thermometers	3350	Tatra Co.:
Chic-Tohe Co.:		Rheumolek Herb Tea No. 3 and
Chic-Tone Co.'s inhalant for		Hematone Herb Tea No. 4 3347
poultry	3360	Weber, Dr. H. O.:
Cosmos Chemical Corp.:	00.44	Enderlins Electrolytic Health
TB-One tablets	3341	Compress (device) 3358
Davis, G. H.:		Weber, H., & Co.:
To-Ne-Ka herbs, Black Eagle		Weber's laxative cold tablets 3346
medicine, and Toneka tonic	0074	Weir, Z. M.:
tablets	3351	
Diez, E. C., Drug Co., Inc.:		methyltestosterone tablets 3343
Rheumolek Herb Tea No. 3 and	00.45	Weir's Drugs & Jewelry. See
Hematone Herb Tea No. 4	3347	Weir, Z. M.

^{1 (3357)} Prosecution contested.



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3361-3380

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs. Washington, D. C., June 18, 1951.

CONTENTS*

	Page		Page
Drug actionable because of poten-		Drugs and devices actionable be-	
tial danger when used accord-		cause of deviation from official	
ing to directions	330	or own standards	337
New drug shipped without effective		Drugs and devices actionable be-	
application	330	cause of false and misleading	
Drugs actionable because of failure		claims	339
to bear adequate directions or		Drugs for human use	339
warning statements	330	Drug for veterinary use	340

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3365, 3367, 3369-3371; omission of, or unsatisfactory, ingredients statements, Nos. 3363, 3365, 3368, 3370; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3363-3371, 3379; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3364-3371, 3379.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3361. Misbranding of mineral oil. U. S. v. 20 Cartons * * * (F. D. C. No. 30503. Sample No. 7051–L.)

LIBEL FILED: January 30, 1951, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 13, 1950, by Certified Pharmacal Co., Inc., from New York, N. Y.

PRODUCT: 20 cartons, each containing 12 1-pint bottles, of mineral oil at Johnstown, Pa.

Nature of Charge: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Infants * * * May be given ½ to 1 teaspoonful," since mineral oil when given to infants, sometimes is aspirated and causes lipoid pneumonia; and, Section 502 (f) (2), the article failed to bear adequate warnings against unsafe dosage and duration of administration since the labeling failed to warn that the article should not be taken at any time other than bedtime, or administered to infants except on advice of a physician.

DISPOSITION: March 27, 1951. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3362. Misbranding of Tibione. U. S. v. 1 Drum * * * (F. D. C. No. 30412. Sample No. 23054-L.)

Libel Filed: February 1, 1951, Southern District of New York; amended libel filed March 1, 1951.

ALLEGED SHIPMENT: On or about January 16, 1951, by the Berkeley Chemical Corp., from Berkeley Heights, N. J.

PRODUCT: 1 drum, containing 43 pounds, of *Tibione*. Examination disclosed that the product consisted of 4-acetylaminobenzal thiosemicarbazone, otherwise known as TB-1 or *Tibione*.

LABEL, IN PART: "Tibione-Synonym."

Nature of Charge: Section 505 (a), the libel charged as a first cause of action that the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

The libel charged also as a second and alternative cause of action that the article was misbranded under Section 502 (f) (1), in that its labeling failed to bear adequate directions for use, and under Section 502 (f) (2), in that its labeling failed to bear such adequate warnings against unsafe dosage or duration of administration as are necessary for the protection of users.

DISPOSITION: March 26, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3363. Misbranding of Benzedrine Sulfate tablets and methyltestosterone tablets.
U. S. v. Oliver W. Anderson (Wyre's Pharmacy). Plea of guilty. Fine

^{*}See also Nos. 3361, 3362.

of \$200, plus costs. (F. D. C. No. 29988. Sample Nos. 52072–K, 52100–K, 72227–K, 72232–K, 72236–K, 72769–K.)

- INFORMATION FILED: November 6, 1950, Northern District of Ohio, against Oliver W. Anderson, trading as Wyre's Pharmacy, Barberton, Ohio.
- INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Ohio, of quantities of Benzedrine Sulfate tablets and methyltestosterone tablets.
- ALLEGED VIOLATION: On or about October 28 and December 29, 1949, and February 21 and March 11, 15, and 16, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions on the labeling of the Benzedrine Sulfate tablets, namely, "As directed" and "¾ tab before breakfast ½ tab before Lunch ¼ tab before Dinner," were not adequate directions for use, and in that the labeling of the methyltestosterone tablets bore no directions for use.

Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

- Disposition: February 26, 1951. A plea of guilty having been entered, the court imposed a fine of \$200, plus costs, against the defendant.
- 3364. Misbranding of Benzedrine Sulfate tablets and methyltestosterone linguets. U. S. v. Rexford Parker (Rex Parker's Pharmacy). Plea of guilty. Fine, \$300. (F. D. C. No. 29997. Sample Nos. 72124-K, 72774-K, 72921-K.)
- Information Filed: On or about November 15, 1950, Eastern District of Kentucky, against Rexford Parker, trading as Rex Parker's Pharmacy, Maysville, Ky.
- Interstate Shipment: From the State of Ohio into the State of Kentucky, of quantities of Benzedrine Sulfate tablets and methyltestosterone linguets.
- ALLEGED VIOLATION: On or about February 9, March 28, and April 4, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.
- DISPOSITION: March 12, 1951. A plea of guilty having been entered, the court imposed a fine of \$300 against the defendant.

- 3365. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Ernest A. Boynes (Boynes Pharmacy). Plea of guilty. Fine, \$200. (F. D. C. No. 29465. Sample Nos. 60241-K to 60245-K, incl.)
- Information Filed: November 3, 1950, Eastern District of Michigan, against Ernest A. Boynes, trading as Boynes Pharmacy, Detroit, Mich.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Michigan, of quantities of Seconal Sodium capsules and Benzedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about January 19, 23, and 25, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged Seconal Sodium capsules failed to bear the name, and the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged Benzedrine Sulfate tablets bore no label containing the common or usual name of the drug.

- DISPOSITION: January 15, 1951. A plea of guilty having been entered, the court imposed a fine of \$200 against the defendant.
- 3366. Misbranding of thyroid tablets, Benzedrine Sulfate tablets, and diethylstilbestrol tablets. U. S. v. Fish O. Norris (Norris Rexall Drug Store). Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30021. Sample Nos. 61891-K, 61892-K, 76418-K, 77125-K.)
- Information Filed: January 15, 1951, Western District of Arkansas, against Fish O. Norris, trading as the Norris Rexall Drug Store, Mena, Ark.
- INTERSTATE SHIPMENT: From the States of Texas, Pennsylvania, and Indiana, into the State of Arkansas, of quantities of thyroid tablets, Benzedrine Sulfate tablets, and diethylstilbestrol tablets.
- ALLEGED VIOLATION: On or about March 6 and 14, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.
- DISPOSITION: February 5, 1951. A plea of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 1 year.

- 3367. Misbranding of sulfadiazine tablets, Benzedrine Sulfate tablets, diethylstilbestrol tablets, sulfadiazine and soda tablets, thyroid tablets, Dexedrine Sulfate tablets, and phenobarbital tablets. U. S. v. James Roy Ivey (Ivey's Drug Store), and Joe G. Bell. Pleas of nolo contendere. Imposition of sentence suspended and each defendant placed on probation for 1 year. (F. D. C. No. 30015. Sample Nos. 46385-K, 46386-K, 61888-K, 61889-K, 77705-K, 77706-K, 77708-K, 77720-K.)
- Information Filed: January 15, 1951, Western District of Arkansas, against James Roy Ivey, trading as Ivey's Drug Store, Mena, Ark., and Joe G. Bell, an employee of the drug store.
- ALLEGED SHIPMENT: From the States of Missouri, Pennsylvania, and Indiana, into the State of Arkansas, of quantities of sulfadiazine tablets, Benzedrine Sulfate tablets, diethylstilbestrol tablets, sulfadiazine and soda tablets, thyroid tablets, Dexedrine Sulfate tablets, and phenobarbital tablets.
- ALLEGED VIOLATIONS: On or about March 6, 10, and 14, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

 James Roy Ivey, the proprietor, was named as defendant in all counts, and Joe G. Bell was named as defendant in those counts charging the repackaging and sale of the sulfadiazine tablets and the Benzedrine Sulfate tablets and 1 lot of the phenobarbital tablets.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the repackaged drugs failed to bear labeling containing directions for use; and, Section 502 (b) (1), the repackaged Benzedrine Sulfate tablets and a portion of the sulfadiazine tablets and the phenobarbital tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warning against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- Disposition: February 5, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence and placed each defendant on probation for 1 year.
- 3368. Misbranding of dextro-amphetamine hydrochloride tablets, thyroid tablets, and amphetamine hydrochloride tablets. U. S. v. W. Calvert Curry (Curry Drug Co.). Plea of guilty. Fine, \$500. (F. D. C. No. 30008. Sample Nos. 23759-K, 23760-K, 23784-K, 53230-K, 53231-K, 53234-K.)
- Information Filed: February 2, 1951, Northern District of Texas, against W. Calvert Curry, trading as the Curry Drug Co., San Angelo, Tex.
- INTERSTATE SHIPMENT: From the States of Missouri, Pennsylvania, and Michigan, into the State of Texas, of quantities of dextro-amphetamine hydrochloride tablets, thyroid tablets, and amphetamine hydrochloride tablets.

ALLEGED VIOLATION: On or about June 28 and July 5 and 11, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (e) (1), the repackaged dextro-amphetamine hydrochloride tablets and the amphetamine hydrochloride tablets failed to bear labels containing the common or usual names of the drugs; and, Section 502 (f) (2), the labeling of the repackaged amphetamine hydrochloride tablets failed to bear warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Disposition: February 3, 1951. A plea of guilty having been entered, the court imposed a fine of \$500 against the defendant.

3369. Misbranding of Dexedrine Sulfate tablets, thyroid tablets, sulfadiazine tablets, and phenobarbital tablets. U. S. v. Mrs. Raymond Morris (City Drug Store), and Tyre L. Delzell. Pleas of nolo contendere. Imposition of sentence suspended and defendants placed on probation for 1 year. (F. D. C. No. 30028. Sample Nos. 76419–K, 76420–K, 77122–K, 77123–K, 77721–K to 77723–K, incl.)

Information Filed: January 15, 1951, Western District of Arkansas, against Mrs. Raymond Morris, trading as the City Drug Store, Mena, Ark., and against Tyre L. Delzell, a pharmacist.

INTERSTATE SHIPMENT: From the States of Pennsylvania, Michigan, and Missouri, into the State of Arkansas, of quantities of Dexedrine Sulfate tablets, thyroid tablets, sulfadiazine tablets, and phenobarbital tablets.

ALLEGED VIOLATION: On or about March 6, 10, and 14, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Nature of Charge: Misbranding, Section 502 (b)(2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f)(1), the labeling of the repackaged drugs bore no directions for use; and Section 502 (b)(1), the repackaged phenobarbital tablets and thyroid tablets and a portion of the Dexedrine Sulfate tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the tablets failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f)(2), the labeling of the repackaged *sulfadiazine tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: February 5, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendants on probation for 1 year.
- 3370. Misbranding of Dexedrine Sulfate tablets, phenobarbital tablets, and sulfadiazine tablets. U. S. v. Thomas G. Hopkins (Hopkins Nyal Drug Store), and James Sorrell. Pleas of nolo contendere. Imposition of sentence suspended and defendants placed on probation for 1 year. (F. D. C. No. 30017. Sample Nos. 61890-K, 72124-K, 77709-K, 77719-K, 77727-K.)
- Information Filed: January 15, 1951, Western District of Arkansas, against Thomas G. Hopkins, trading as the Hopkins Nyal Drug Store, Mena, Ark., and James Sorrell, an employee at the store.
- Interstate Shipment: From the States of Pennsylvania and Missouri into the State of Arkansas, of quantities of *Dexedrine Sulfate tablets*, phenobarbital tablets, and sulfadiazine tablets.
- ALLEGED VIOLATION: On or about March 6, 10, 13, and 14, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Thomas G. Hopkins was named as a defendant in all counts, and James Sorrell was named as a defendant in all counts, with the exception of the count charging a violation resulting from one sale of *phenobarbital tablets*.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the tablets failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the *Dexedrine Sulfate tablets* and a portion of the *sulfadiazine tablets* failed to bear labels containing the common or usual names of the drugs; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- Disposition: February 5, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence against the defendants and placed each defendant on probation for 1 year.
- 3371. Misbranding of Seconal Sodium capsules. U. S. v. Samuel P. Rottenberg (Cortland Pharmacy). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 29466. Sample Nos. 60205-K to 60207-K, incl., 60209-K.)
- Information Filed: November 3, 1950, Eastern District of Michigan, against Samuel P. Rottenberg, trading as the Cortland Pharmacy, Detroit, Mich.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of Michigan, of quantities of Seconal Sodium capsules.

ALLEGED VIOLATION: On or about January 17, 18, 21, and 25, 1950, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and sold without a prescription, which acts resulted in the capsules being misbranded.

Nature of Charge: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules bore no label containing the name and place of business of the manufacturer, packer, or distributor, and no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules bore no directions for use.

DISPOSITION: January 11, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$200.

3372. Misbranding of Lang's Mineral Iron and Aluminum Sulfate. U. S. v. 15
Pounds, etc. (F. D. C. No. 30343. Sample Nos. 86437-K to 86440-K, incl.)

LIBEL FILED: December 19, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about October 7 and 25, 1950, and on other dates in 1950, by Margaret Lange, from Portland, Oreg.

PRODUCT: Lang's Mineral Iron and Aluminum Sulfate. 15 pounds in bulk; 25 envelopes, each containing 1/3 ounce; 21 boxes, each containing 12 capsules; and 12 12-ounce bottles containing the product in solution, at Lang's Mineral Wonder, Los Angeles, Calif.

Also in the possession of the consignee were 8,000 empty envelopes, 200 labels for the capsules, 1,000 labels for the solution, and 1,000 copies of a folder entitled "Lang's Mineral Wonder."

RESULTS OF INVESTIGATION: The product was shipped, labeled as described below. The consignee repackaged the article into envelopes, each containing ½ ounce; into boxes, each containing 12 capsules; and into bottles, each containing 12 ounces of a solution consisting of 1 pound of the article to 5 gallons of water. The consignee also caused the printing of the envelopes, the box and bottle labels, and a folder entitled "Lang's Mineral Wonder." This folder was given to prospective customers at the consignee's place of business and was mailed in response to inquiries.

LABEL, IN PART: (Bulk shipment) "Lang's Mineral Iron and Aluminum Sulfate"; (repackaged, in envelopes) "Lang's Mineral Wonder * * * Net Contents: ½ oz."; (repackaged, in boxes) "Lang's Mineral Wonder * * * Lang's Female Capsules"; and (repackaged, in bottles) "Lang's Mineral Wonder * * * Net Contents: 12 oz."

NATURE OF CHARGE: Misbranding (bulk shipment), Section 502 (f) (1), the labeling failed to bear adequate directions for use since the labeling bore no directions for use. The article was misbranded in this respect when introduced into, and while in, interstate commerce.

Further misbranding (repackaged drug in envelopes, boxes, and bottles), Section 502 (a), certain statements in the accompanying folder entitled "Lang's Mineral Wonder" were false and misleading. These statements represented and suggested that the article would be effective as a treatment for

physical troubles; that it would help reach the cause of a wide variety of conditions; that it would end conditions that bring pain and distress; and that it would furnish the system with minerals essential for it. The article would not be effective in the treatment of the conditions and for the purposes stated and implied.

Further misbranding, Section 502 (a), certain statements on the label of the boxes of capsules were false and misleading since the statements represented and suggested that the article would be effective as a treatment for diseases of females, whereas it would not be effective as a treatment for diseases of females.

Further misbranding (envelopes, boxes, and bottles), Section 502 (a), the statements which appeared on the envelopes "Silica (SiO₂), Sodium & Potassium Oxide (NA₂O & K₂O), Phosphates (P₂O₅), Iron Oxide (FE₂O₅), Aluminum Oxide (AL₂O₅), Sulphates (SO₅), Moisture @ 105° C, Water (Combined) (By Difference)" and the statements which appeared on the label of the bottles containing the solution—

	Parts per	Grains per
	million	gallon
Silica (SiO ₂)	5.0	.29
Iron Oxide (FE ₂ O ₃)	5120.0	-299.00
Aluminum Oxide (Al ₂ O ₃)	1332.0	77.79
Sulphuric Anhydride (SO ₃)	9720.0	567.65
Total Solids	16177.0	944.73

were misleading in that they failed to reveal the material fact that, when taken as directed, the article would supply no therapeutically useful substance; and the statements on the label of the boxes containing the capsules "Silica (SiO₂) 0.08% Sodium & Potassium Oxide (Na₂O & K₂O) trace, Phosphates (P₂O₅) trace, Iron Oxide (Fe₂O₅) 6.26%, Sulphates (SO₃) 39.92% Moisture @ 105° C 14.02%, Water (Combined) (By Difference) 19.50%" were misleading since they failed to reveal the material fact that the iron and aluminum sulfates were the only constituents of the article that, when taken as directed, would produce any significant physiologic effect. The product in the envelopes, boxes, and bottles was misbranded while held for sale after shipment in interstate commerce.

Disposition: February 8, 1951. Florence Potter, also known as Florence Wilson, trading as Lang's Minerals, Los Angeles, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be relabeled, under the supervision of the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3373. Adulteration and misbranding of Succidol capsules. U. S. v. Calvital Co., Inc., and Alexander S. Race. Pleas of guilty. Fine of \$200 against corporation; fine of \$4 against individual remitted. (F. D. C. No. 29476. Sample No. 57251-K.)

Information Filed: January 12, 1951, Southern District of New York, against Calvital Co., Inc., Mount Vernon, N. Y., and Alexander S. Race, president of the corporation.

ALLEGED SHIPMENT: On or about October 27, 1949, from the State of New York into the State of Connecticut.

Nature of Charge: Adulteration, Section 501 (c), each capsule of the article purported and was represented to contain 4 grains of para-aminobenzoic acid as the sodium salt, whereas each capsule of the article contained less than 4 grains of para-aminobenzoic acid as the sodium salt.

Misbranding, Section 502 (a), the statement in the labeling of the article which represented and suggested that each capsule of the article contained 4 grains of para-aminobenzoic acid as the sodium salt was false and misleading.

The information alleged also that another product, namely, Calvital capsules, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 14, 1951. Pleas of guilty having been entered, the court imposed a fine of \$200 against the corporation and a fine of \$4 against the individual. The court remitted the individual's fine.

3374. Adulteration and misbranding of prophylactics. U. S. v. 8 Gross * * * *. (F. D. C. No. 30694. Sample No. 31877-L.)

LIBEL FILED: March 12, 1951, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 29, 1950, by the Star Sales Co., from New Orleans, La.

Product: 8 gross of *prophylactics* at St. Louis, Mo. Examination of samples showed that 2.1% were defective in that they contained holes.

LABEL, IN PART: "Silver-Tex Manufactured by the Killian Mfg. Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Tested * * * For your protection," "Prophylactic," and "Prophylactics" were false and misleading as applied to an article containing holes.

DISPOSITION: April 5, 1951. Default decree of condemnation and destruction.

3375. Adulteration and misbranding of prophylactics. U. S. v. 7 Gross * * * * (F. D. C. No. 30667. Sample Nos. 32060-L, 32062-L.)

LIBEL FILED: February 27, 1951, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about October 5, 1950, and January 24, 1951, by the Dean & Adelsperger Co., from Kansas City, Mo.

PRODUCT: 7 gross of *prophylactics* at Little Rock, Ark. Examination of samples showed that 2.6 percent were defective in that they contained holes.

LABEL, IN PART: "Genuine Sekurity Mfd. by Dean Rubber Mfg. Co. N. Kansas City, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Sekurity Prophylactics * * * Scientifically tested for your protection * * * an aid in preventing venereal diseases" were false and misleading as applied to an article containing holes.

DISPOSITION: March 27, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

- 3376. Misbranding of Pan-Tone. U. S. v. Pan-Tone Drug Co. Plea of nolo contendere. Sentence deferred. (F. D. C. No. 30000. Sample No. 47665–K.)
- Information Filed: December 11, 1950, Southern District of Florida, against the Pan-Tone Drug Co., a corporation, Jacksonville, Fla.
- ALLEGED SHIPMENT: On or about March 6, 1950, from the State of Florida into the State of Virginia.
- PRODUCT: Analysis disclosed that the product was a solution containing 46 percent of epsom salt, and ferric iron equivalent to 1.4 percent of ferric chloride solution.
- Label, IN Part: "Pan-Tone * * * Medicine * * * Active Ingredients Solution of Ferric Chloride, Citric Acid, Glycerine, Epsom Salts (Magnesium Sulphate), and U.S. Certified Food Coloring."
- Nature of Charge: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "How Many Years Are You Going to Live" were false and misleading. The statements represented and suggested that the article would be efficacious in the treatment of rheumatism, neuralgia, neuritis, high blood pressure, lumbago, sciatica, constipation, nervousness, headaches, biliousness, kidney disorders, dizziness, backaches, swollen feet, pains in the bones, joints, and muscles, anemia, dyspepsia, indigestion, heartburn, bloating, boils, a tired, broken-down feeling, diabetes, bleeding piles, and diarrhea; and that the article would be efficacious to promote longer life, purify the blood, build the body, and to restore the appetite. The article would not be efficacious for the purposes represented.
- DISPOSITION: January 15, 1951. A plea of nólo contendere having been entered the defendant was judged guilty as charged in the information, and sentence was deferred for 1 year, until January 1952, during which time the defendant was to bring the labeling of the product into full compliance with the law.
- 3377. Misbranding of Lar tablets and Looz tablets. U. S. v. 69 Bottles, etc. (F. D. C. No. 30372. Sample Nos. 59398-K, 59399-K.)
- LIBEL FILED: January 12, 1951, Northern District of Indiana.
- ALLEGED SHIPMENT: On or about October 2 and November 7 and 22, 1950, by Looz, Inc., from Chicago, Ill.
- PRODUCT: 69 40-tablet bottles of Lar tablets and 92 30-tablet bottles of Looz tablets at Hammond, Ind., together with a number of streamers entitled "Take Lar," "Lumbago-Arthritis Rheumatism," and "Reduce Hips & Waist."
- Label, In Part: (Bottles) "Lar enteric coated Tablets * * * Ingredients: Vit B₁ (Thiamine Hydrochloride, Sodium Salicylate, aspirin (Acetyl Salicylic Acid), Caffeine Alkaloid" and "Looz * * * Ingredients: Dried Magnesium Sulfate, Exsiccated Sodium Sulfate, Magnesium Carbonate, Magnesium Oxide."
- NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels and streamers were false and misleading. The statements represented and suggested that the *Lar tablets* were a competent and effective treatment for lumbago, arthritis, and rheumatism, and that the *Looz tablets* would be effective for providing weight reduction, whereas the articles would not be effective for such purposes.
- Disposition: March 7, 1951. Default decree of condemnation and destruction.

^{*}See also Nos. 3372-3375.

3378. Misbranding of bone phosphate flour and bone phosphate wafers. U. S. v. 1 Opened Barrel, etc. (F. D. C. No. 30299. Sample Nos. 47292–K to 47295–K, incl.)

LIBEL FILED: November 29, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 4 and 15 and September 13 and 18, 1950, from Calumet City, Ill., and Kalamazoo, Mich.

PRODUCT: 1 opened barrel containing 250 pounds of bone phosphate flour and 3 unopened drums and 1 opened drum containing a total of 110,500 bone phosphate wafers at Loupurex, Pa., together with a number of copies of a magazine entitled "Prevention."

RESULTS OF INVESTIGATION: The products were being repackaged and relabeled by the consignee, Nu-Age Products, Loupurex, Pa. At the time of seizure, there were on hand approximately 200 labels reading, in part, "75 1-Gram Wafer-Tablets Bone Phosphate," approximately 100 labels reading, in part, "300 1-Gram Wafer-Tablets Bone Phosphate," and approximately 500 labels reading, in part, "Bone Phosphate 16 Ounces."

There were also in possession of the consignee about 800 copies of a magazine entitled "Prevention," copies of which were sent to prospective customers.

Nature of Charge: Misbranding, Section 502 (a), certain statements in the magazine were false and misleading. The statements represented and suggested that the articles were effective to prevent pollomyelitis, whereas the articles were not effective for such purpose. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 18, 1951. Default decree of condemnation and destruction.

3379. Misbranding of Le Joi device. U. S. v. 70 Devices, etc. (F. D. C. No. 30159. Sample No. 91434–K.)

LIBEL FILED: November 21, 1950, District of North Dakota.

Alleged Shipment: On or about August 15, 1950, by the Krolop Co., from Bagley, Minn.

PRODUCT: 70 Le Joi devices at Enderlin, N. Dak., together with a number of leaflets entitled "Instructions Le Joi." Examination showed that the device consisted of a rubber tube closed at one end by a plastic clamp, the base of which was extended for some distance into the tube, and closed at the other end by a metal knob. A movable ball inside the tube at this end regulated the size. A metal band about % inch wide covered the center portion of the tube.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device contained statements which were false and misleading since the device was not effective for the purpose represented, namely, stimulating the male sex organ.

Further misbranding, Sections 502 (b) (1) and (2), the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

DISPOSITION: March 2, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3380. Misbranding of Dr. Jelen's Liquid Hog Medicine. U. S. v. 7 Jugs, etc. (F. D. C. No. 30435. Sample No. 31353-L.)

LIBEL FILED: February 20, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: On or about October 9, 1950, by Dr. Jelen's Veterinary Supply Corp., from Omaha, Nebr.

PRODUCT: 7 1-gallon jugs of *Dr. Jelen's Liquid Hog Medicine* at Viola, Ill., together with a number of pamphlets entitled "Dealer's Price List April, 1950 Dr. Jelen's Veterinary Supply Corp." and "Customer's Price List April, 1950."

Analysis disclosed that the product consisted essentially of potassium arsenite, sodium hydroxide 11 percent, sodium carbonate, sodium thiosulfate, sodium phosphate, potassium iodide (trace), creosote and anise oil, and licorice extract. Niacin (nicotinic acid), declared on the label, also may have been present but was not determined by analysis.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the pamphlets were false and misleading since the article was not effective for the purposes stated and implied and was not capable of fulfilling the promises and benefit made for it. The statements represented and suggested that the article was efficacious in the treatment of necrotic enteritis "necro," and black scours; that it was helpful as a tonic; that it would help to keep the brood sow in good condition and to produce litters free from "necro"; that it would help prevent losses at weaning time; that it would help to keep hogs free from "necro"; and that it would be of value for slow, sluggish, out-of-condition poultry flocks.

The article was alleged also to be misbranded under the provisions of the Caustic Poison Act, as reported in notices of judgment under that act.

DISPOSITION: April 13, 1951. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3361 TO 3380

PRODUCTS

N. J. No.	N. J. No.
Amphetamine hydrochloride tab-	Looz tablets 3377
lets and dextro-amphetamine	Methyltestosterone linquets 3364
hydrochloride tablets 3368	tablets 3363
Arthritis, remedy for 3377	Mineral Iron and Aluminum Sul-
Benzedrine Sulfate tablets 3363-3367	fate, Lang's 3372
Bone phosphate flour and bone	Mineral oil 3361
phosphate wafers 3378	Pan-Tone 3376
Devices 3374, 3375, 3379	Phenobarbital tablets3367,
Dexedrine Sulfate tablets 3367,	3369, 3370
3369, 3370	Poliomyelitis, remedy for 3378
Dextro-amphetamine hydrochlo-	Prophylactics 3374, 3375
ride tablets and ampheta-	Reducing, remedy for 3377
mine hydrochloride tablets_ 3368	Rheumatism, remedy for 3377
Diethylstilbestrol tablets 3366, 3367	Seconal Sodium capsules 3365, 3371
Jelen's, Dr., Liquid Hog Medi-	Succidol capsules 3373
cine 3380	Sulfadiazine tablets 3367, 3369, 3370
Lang's Mineral Iron and Alumi-	and soda tablets 3367
num Sulfate 3372	Thyroid tablets 3366-3369
Lar tablets 3377	Tibione (TB-1) 3362
Le Joi device 3379	Veterinary preparation 3380
Liquid Hog Medicine, Dr.	,
Jelen's 3380	

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N.	J. No.	N.	J. No.
Anderson, O. W.:		Ivey's Drug Store. See Ivey,	
Benzedrine Sulfate tablets	3363	J. R.	
Bell, J. G.:		Jelen's, Dr., Veterinary Supply	
sulfadiazine tablets, Benze-		Corp.:	
drine Sulfate tablets, and		Dr. Jelen's Liquid Hog Medi-	
phenobarbital tablets	3367	cine	3380
Berkeley Chemical Corp.:		Killian Mfg. Co.:	
Tibione (TB-1)	3362	prophylactics	3374
Boynes, E. A.:		Krolop Co.:	
Seconal Sodium capsules and		Le Joi device	3379
Benzedrine Sulfate tablets	3365	Lange, Margaret:	
Boynes Pharmacy. See Boynes,	18	Lang's Mineral Iron and Alu-	
E. A.		minum Sulfate	3372
Calvital Co., Inc.:		Lang's Mineral Wonder:	
Succidol capsules	3373	Lang's Mineral Iron and Alu-	
Certified Pharmacal Co., Inc.:		minum Sulfate	3372
mineral oil	3361	Looz, Inc.:	
City Drug Store. See Morris,		Lar tablets and Looz tablets	3377
Mrs. Raymond.		Morris, Mrs. Raymond:	
Cortland Pharmacy. See Rotten-		Dexedrine Sulfate tablets, thy-	
berg, S. P.		roid tablets, sulfadiazine	
Curry, W. C.:		tablets, and phenobarbital	
dextro-amphetamine hydro-		tablets	3369
chloride tablets, thyroid tab-		Norris, F. O.:	
lets, and amphetamine hydro-		thyroid tablets, Benzedrine	
chloride tablets	3368	Sulfate tablets, and diethyl-	
Curry Drug Co. See Curry, W. C.		stilbestrol tablets	3366
Dean & Adelsperger Co.:		Norris Rexall Drug Store. See	
prophylactics	3375	Norris, F. O.	
Dean Rubber Mfg. Co.:		Nu-Age Products:	
prophylactics	3375	bone phosphate flour and bone	
Delzell, T. L.:		phosphate wafers	3378
Dexedrine Sulfate tablets, thy-		Pan-Tone Drug Co.:	
roid tablets, sulfadiazine		Pan-Tone	3376
tablets, and phenobarbital		Parker, Rexford:	
tablets	3369	Benzedrine Sulfate tablets and	
Hopkins, T. G.:		methyltestosterone linguets_	3364
Dexedrine Sulfate tablets, phe-		Parker's, Rex, Pharmacy. See	
nobarbital tablets, and sul-		Parker, Rexford.	
fadiazine tablets	3370	Race, A. S.:	
Hopkins Nyal Drug Store. See		Succidol capsules	3373
Hopkins, T. G.		Rottenberg, S. P.:	
Ivey, J. R.:		Seconal Sodium capsules	3371
sulfadiazine tablets, Benze-		Sorrell, James:	
drine Sulfate tablets, diethyl-		Dexedrine Sulfate tablets and	
stilbestrol tablets, sulfadi-		sulfadiazine tablets	3370
azine and soda tablets,		Star Sales Co.:	
thyroid tablets, Dexedrine		prophylactics	3374
Sulfate tablets, and pheno-		Wyre's Pharmacy. See Ander-	
harbital tablets	3367	son O W	

HERRINGE PRINTER

1911 1 0000



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Agriculture

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

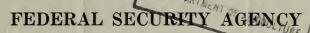
• \$15 per year

U.S. DEPARTMENT OF ABRIBULTURE

CURRENT SERIAL RECORD

U. S. GOVERNMENT PRINTING OFFICE: 1981

Page



FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to Section 705 of the Food, Drug, and Cosmetic Act]

3381-3383

DRUGS AND DEVICES

The cases reported under Nos. 3381 and 3383 were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency; the case reported under No. 3382 was instituted in the District Court of the District of Columbia by Mytinger & Casselberry, Inc. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs. Washington, D. C., August 7, 1951.

CONTENTS

N. J. No.	
3381. Seizure actions against various quantities of Nutrilite Food Supplement	
3382. Injunction suit filed by Mytinger & Casselberry, Inc., against Osca R. Ewing, Paul B. Dunbar, Charles W. Crawford, Louis D. Elliott George P. Larrick, and Tom C. Clark	,
3383. Injunction suit filed by the United States, against Mytinger & Casselberry, Inc., Nutrilite Products, Inc., Lee S. Mytinger William S. Casselberry, and Carl F. Rehnborg	354

3381. Alleged misbranding of Nutrilite Food Supplement. U. S. v. 91 Packages, etc. (and 9 other seizure actions). Claimant files answers denying product misbranded. Court denies claimant's motion to consolidate and remove libels to Southern District of California for trial; libels ordered removed and consolidated for trial in Northern District of California. Consent decrees entered providing for delivery of product to charitable institutions. (F. D. C. Nos. 25789, 25810, 25975, 26068, 26085, 26123, 26141 to 26144, incl. Sample Nos. 875-K, 7496-K, 9082-K, 9083-K, 9095-K, 9096-K, 9113-K, 15250-K, 20745-K, 25560-K, 37758-K, 40671-K.)

LIBELS FILED: Between the dates of September 30, 1948, and January 14, 1949, in the District of New Jersey, Southern and Western Districts of New York, Southern District of Florida, District of Nebraska, District of Minnesota, Eastern and Western Districts of Washington, and Northern District of Illinois.

ALLEGED SHIPMENT: Between the dates of July 25 and December 15, 1948, by Mytinger & Casselberry, Inc., from Long Beach, Calif.

PRODUCT: 180 packages of Nutrilite Food Supplement and 34 packages of Nutrilite Capsules No. 5 at Belleville, N. J., accompanied by a number of copies of a 58-page edition and a 36-page edition of a booklet entitled "How to Get Well and Stay Well" and a number of copies of booklets entitled "NutriLife Vol. 1 No. 1" and "NutriLife Vol. 1 No. 3"; 19 packages of Nutrilite Food Supplement at New York, N. Y., accompanied by a number of copies of a 58-page edition of the booklet "How to Get Well and Stay Well" and a number of booklets entitled "Sales Manual"; 12 packages of Nutrilite Food Supplement at Eggertsville, N. Y., accompanied by a number of copies of a 58page edition of the booklet "How to Get Well and Stay Well"; 20 packages of Nutrilite Food Supplement and 6 boxes of Nutrilite Mineral Tablets at St. Petersburg, Fla., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well" and a number of copies of leaflets entitled "NutriLife Vol. 1 No. 1 [or "No. 3"]"; 654 packages of Nutrilite Food Supplement, accompanied by a number of copies of a 36-page edition of the booklet "How to Get Well and Stay Well," and 51 sales kits each containing 2 copies of the 36-page edition of the booklet "How to Get Well and Stay Well" and 3 vials of alfalfa leaves, order blanks, and other printed matter at Minden, N. J.; 200 packages of Nutrilite Food Supplement at Clarkfield, Minn., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; 35 packages of Nutrilite Food Supplement at Seattle, Wash., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; 19 packages of Nutrilite Food Supplement at Spokane, Wash., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; and 78 packages of Nutrilite Food Supplement at Oak Park, Ill., accompanied by a number of copies of the 58-page edition and the 42-page edition of the booklet "How to Get Well and Stay Well."

Each package of *Nutrilite Food Supplement* contained 2 bottles of Nutrilite Multiple Vitamin Dietary Supplement Capsules and 1 box of Nutrilite Mineral Tablets.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the product was not effective to accomplish the results stated and implied. (A description of the labeling and excerpts therefrom and the charges set out in the libels based on the labeling are indicated in the complaint for injunction filed by the Government in the Southern District of California to enjoin Mytinger and Casselberry, Inc., and others from introducing the product Nutrilite Food Supplement in interstate commerce under labeling which misbranded it, as reported in notice of judgment No. 3383.)

Disposition: Mytinger & Casselberry, Inc., Long Beach, Calif., entered its appearance as claimant in all actions and filed answers denying that the product was misbranded as alleged in the libels. On April 6, 1948, the claimant moved to consolidate and remove the cases to its home district, the Southern District of California. Decision on the motion was held in abeyance pending the termination of the injunction proceedings filed by the claimant to enjoin the Government from making multiple seizures of the claimant's product, as reported in notice of judgment No. 3382.

Upon termination of the injunction suit against the Government, the motion for removal of the seizure actions to the Southern District of California was denied, and the libels were ordered consolidated and removed to the Northern District of California. The court delivered the following opinion:

Fake, Chief Judge: "The issues here arise on motions to consolidate and remove some ten libel actions instituted by the United States in divers jurisdictions about the country. They involve the same parties and substantially the same issues bearing on alleged violations of the Federal Food, Drug, and

Cosmetic Act, 21 U.S.C.A. 301 et seq.

"The above act expressly provides for the seizure of drugs in interstate commerce for violations of the act, the seizures to be made by libels as in admiralty. It further provides that when such libel proceedings are pending in two or more jurisdictions, a claimant may apply to the Court of one such jurisdiction for an order consolidating such proceedings for trial in one district, and in the words of the statute that district shall, in the absence of 'good cause to the contrary,' be 'a district of reasonable proximity to claimant's principal place of business.' The weight of authority is that 'a district of reasonable proximity to claimant's principal place of business' excludes the district of claimant's place of business. United States v. 29 Bottles * * * Ocean Lax, 44 Fed. Supp. 317; United States v. Six Dozen Bottles * * * Dr. Peter's Kuriko, 55 Fed. Supp. 458; United States v. 600 Units * * * Neu-Ovo, 60 Fed. Supp. 144; United States v. 26 Dozen Bottles * * * Wheatamin Brand Cevigards, 60 Fed. Supp. 626. "I conclude that under this statute the district of reasonable proximity

"I conclude that under this statute, the district of reasonable proximity for the trial of the actions considered here is the United States District Court

for the Northern District of California, Southern Division.

"Claimants argue that Title 28 U.S. C. A. 1404 (a) is applied

"Claimants argue that Title 28 U. S. C. A. 1404 (a) is applicable. That statute is directed toward Change of Venue and provides:

For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

"There is no doubt but that the actions under consideration are civil actions, Ex Parte Collett, 337 U. S. 55, but are they such actions as might have been brought in any other districts than those in which they were brought? The answer is no, because they were brought as actions in rem, and as such could be commenced only where the res was found at the time. 28 U. S. C. A. 1395 (b). United States v. 11 Cases * * * Ido-Pheno-Chon (Civil Action 5145, District Court of the United States, District of Oregon, opinion by Chief Judge Fee, filed August 31, 1950, as yet unreported).

"An order of consolidation will be entered for trials in the Northern District

of California, Southern Division."

On April 10, 1951, upon stipulation of the parties that the cases presented no questions for adjudication for the reasons that (1) the products under seizure may have become below label potency and therefore unmarketable by reason of lapse of time and that (2) the use of the labeling involved had been covered by a final consent decree entered in the Southern District of California in the injunction suit referred to hereinbefore, the court ordered that the products be delivered to charitable institutions, with the explanation that the products may be below label potency, and that any literature in possession of the marshal be sent to Mytinger & Casselberry, Inc., Long Beach, Calif., to be disposed of in accordance with the said decree.

3382. Suit for injunction to restrain prosecution of pending seizures of Nutrilite Food Supplement; to enjoin institution of additional seizures; and to test constitutionality of Section 304 (a) of the Act and administrative action taken thereunder. Mytinger & Casselberry, Inc., v. Oscar R. Ewing, Paul B. Dunbar, Charles W. Crawford, Louis D. Elliott, George P. Larrick, and Tom C. Clark. Motion for dismissal denied; defendants' petition to Supreme Court for writ of prohibition denied. Tried before three-judge court. Decree of permanent injunction; decree reversed upon appeal to Supreme Court.

COMPLAINT FILED: On December 30, 1948, Mytinger & Casselberry, Inc., of Long Beach, Calif., filed in the District of Columbia a complaint for temporary and permanent injunction and temporary restraining order against Oscar R. Ewing, Administrator, Federal Security Agency; Paul B. Dunbar, Commissioner, Charles W. Crawford, Associate Commissioner, Louis D. Elliott, Assistant Commissioner, and George P. Larrick, Assistant Commissioner, Food and Drug Administration; and Tom C. Clark, Attorney General of the United States.

NATURE OF COMPLAINT: The complaint alleged that the plaintiff, Mytinger & Casselberry, Inc., had established a large and lucrative buisness in the distribution of *Nutrilite Food Supplement*, which is an encapsulated concentrate of alfalfa, parsley, and water cress, fortified with vitamins and minerals; that distribution was made by direct contact with consumers through field agents who used a sales booklet entitled "How to Get Well and Stay Well"; and that the booklet contained a general discussion of nutrition, the need for vitamins and minerals, and the consequences of the lack of such factors in the diet, but contained no statements that were false, fraudulent, or misleading.

The complaint recited a history of the firm's contacts with the Food and Drug Administration, which allegedly resulted in elimination of all false labeling claims, and stated that, nevertheless, an indictment had been returned against the firm.

The complaint alleged further that the defendants had caused to be initiated a number of libel actions against, and had been instrumental in having a number of state and local embargoes placed upon, the products of the plaintiff; that additional libel actions were in contemplation; that all such seizure for condemnation actions involved the same issues of law and fact, and that one such case would result in determination of the validity of the claims made by the plaintiff; and the multiple seizure actions had tied up large amounts of Nutrilite, which was subject to deterioration and loss of potency with the passage of time, and would be of no value to the plaintiff when the cases had been determined; that no necessity existed for harassing the plaintiff with numerous actions; that the business and good will of the plaintiff were threatened by the arbitrary and illegal actions of the several defendants: and

that the prosecution of such libels in various parts of the United States was unnecessarily oppressive and expensive to the plaintiff since plaintiff's business would be destroyed before an adjudication on the merits could be made.

The complaint alleged also that multiple seizure actions were not authorized by Section 304 (a) of the Act because (1) there had been no prior judgment in favor of the United States; (2) the product was not dangerous to health; and (3) no finding had been served upon the plaintiff to the effect that the labeling of the product was fraudulent or would be in a material respect misleading, to the injury or damage of the purchaser or consumer. The complaint alleged also that the application to its product of a finding which had been made without hearing and which had not been served upon it would deprive it of property without due process of law; that the Food and Drug Administration refused to stipulate or approve a stipulation so as to permit removal of the libels to the Southern District of California, where witnesses were available, thus depriving plaintiff of an opportunity adequately to defend the case; that the defendant officials of the Federal Security Agency were pursuing a course of enforcement over and beyond their prescribed statutory duties, with a design to harass and ruin plaintiff prior to any adjudication on the merits; that the Administrative Procedure Act provides for judicial review of any finding that may have been made as a basis for multiple seizures; and that the finding should be reviewed and set aside because it was an arbitrary, capricious, and unreasonable exercise of discretion in that it was not founded upon fact, and in the circumstances of the case, deprived plaintiff of property without due process of law in violation of the Fifth Amendment.

MOTION TO DISMISS

Following the filing of the complaint, a motion for dismissal of the action and for summary judgment was filed on behalf of the defendants. The motion was based on the grounds that (1) the defendant officials of the Federal Security Agency had no control over the litigation and no power to comply with the prayers of the complaint; (2) the recommendations of multiple seizure actions were made in accordance with Section 304 (a) of the Act, and the findings on which the recommendations were based were not subject to judicial review; (3) the complaint failed to state a claim upon which relief could be granted against the Attorney General; (4) the complaint sought relief which was beyond the Court's authority; (5) the complaint failed to state a claim for equitable relief; and (6) the public interest precluded temporary injunctive relief.

After consideration of the briefs and arguments of counsel, Judge Pine of the United States District Court for the District of Columbia, on January 26, 1949, denied the motion without prejudice on the ground that since the initial determination of probable cause had been made by the Food and Drug Administration defendants acting under delegated authority, rather than by the Federal Security Administrator, the determinations were improper.

On Januay 28, 1949, the Acting Federal Security Administrator, J. Donald Kingsley, made determinations of probable cause. The defendants' motion to dismiss was then renewed. On March 4, 1949, Judge Pine granted defendants' motion to dismiss, with leave to the plaintiff to amend to attack the constitutionality of Section 304 (a) of the Act.

AMENDED COMPLAINT

An amended complaint to present the constitutional question was thereupon filed by the plaintiff on the same day, i. e., March 4. The amended complaint

alleged substantially the same facts as were alleged in the original complaint, and, in addition, alleged that Section 304 (a) was repugnant to the due process clause, as it failed to afford plaintiff an opportunity for a hearing prior to the determinations of probable cause.

On March 7, 1949, upon plaintiff's motion for a temporary restraining order, Judge Tamm of the United States District Court of the District of Columbia entered such order to restrain the defendants from instituting and prosecuting any further and additional libel for condemnation actions against plaintiff's product, known as *Nutrilite Food Supplement*, based upon alleged misbranding of the product. In addition it was ordered that the temporary restraining order should remain in force until a hearing and determination of plaintiff's application for an interlocutory injunction could be made by a three-judge statutory court to be appointed to hear and determine such matters.

THREE-JUDGE COURT

On March 15, 1949, Judge Bennett C. Clark of the United States Court of Appeals for the District of Columbia and Judges T. Alan Goldsborough and Edward A. Tamm of the United States District Court for the District of Columbia were designated to serve as members of the three-judge statutory court to hear and determine the action. A motion for dismissal of the action was filed on behalf of the defendants, and on April 6, 1949, argument on the motion was heard before the three-judge court. At this time, the court informally directed counsel for the parties to stipulate that the restraining order should be continued in effect, to prepare for a pretrial conference, and to prepare for a trial on the merits as to whether the labeling was materially misleading. The defendants' counsel refused to stipulate, and the court thereupon denied the motion to dismiss. On the same day, the three-judge court, without hearing evidence and without making findings of fact or conclusions of law, entered an order in the nature of a temporary injunction, directing that the defendants be restrained and enjoined temporarily pending final judgment, from continuing or causing to be continued the prosecution of any of the pending libel actions referred to in the complaint, other than the first libel action referred to therein, and from instituting and causing to be instituted further libel actions against, or seizures of, Nutrilite Food Supplement until final judgment in the instant case.

PRETRIAL CONFERENCE

On April 13, 1949, a pretrial conference was held. During the course of this conference, counsel for the defendants objected to the trial (1) because Judge Pine's ruling was the law of the case on everything but the constitutional issue and (2) because the court was without jurisdiction to go into the question of misleading labeling in that the Act vests exclusively in the Federal Security Administrator the function of determining "whether there is probable cause to believe that the labeling involved in this case is materially misleading to the injury or damage of the purchaser or consumer," as a preliminary to the institution of multiple libel actions. Defendants' counsel also requested the court to vacate its temporary restraining order and preliminary injunction of April 6 for the reason that findings of fact and conclusions of law had not been issued. The defendants' objections having been overruled, the case was scheduled for trial on May 9, 1949. With reference to the issue to be tried, Judge Tamm stated as follows: "The issue before the court fundamentally, insofar as testimony is concerned, will be the question of misleading

labeling in the use of the book 'How to Get Well and Stay Well * * *.' There are two questions before the court, one, a question of fact as to whether the labeling is misleading and, two, the question of whether the action which the defendant in the case took violated the constitutional rights of the plaintiff." Discussion also was had at the conference in regard to the filing by the defendants of an answer to the complaint, and, in accordance with the understanding then reached, such answer was filed on April 21, 1949. The answer (1) challenged the court's jurisdiction to try the issue as to whether the labeling is materially misleading; (2) asserted that the suit was in substance and effect against the United States, which had not consented to be sued; (3) admitted some and denied others of the allegations of the amended complaint, the essential defense being that the defendants acted under Section 304 (a) in requesting the institution of 10 suits against 10 shipments of an allegedly misbranded drug; and (4) denied that the defendants acted to harass the plaintiff or that they acted in excess of their statutory authority.

SUBPOENAS DUCES TECUM

Following the conference, the plaintiff served upon the defendant officials of the Federal Security Agency subpoenas duces tecum calling for the production of all records of the Federal Security Agency relating to the plaintiff. The defendants moved to quash the subpoena with respect to defendant Kingsley, on the ground that the subpoena was too vague, broad, and unreasonable, and that it constituted unauthorized probing of the Administrator's mental processes in making his decisions. On April 19, 1949, argument on the motion was heard before Judge Clark.

On April 29, 1949, the court entered an order denying the motion and directing the defendants to produce all records in the case insofar as they related to the decisions of probable cause made in the case. The order excluded the records that related to the criminal action then pending in the United States District Court for the Southern District of California, against Lee S. Mytinger and William S. Casselberry, secretary and president, respectively of Mytinger & Casselberry, Inc. It was ordered also that the defendants should have the right to inspect all documents in possession of the plaintiff or any of its officials or employees, relating to the product involved in the case.

PETITION FOR WRITS OF PROHIBITION AND MANDAMUS

On or about May 9, 1949, a petition for writs of prohibition and/or mandamus was filed in the Supreme Court on the ground that the three-judge court proposed action in excess of its jurisdiction in undertaking a trial de novo on the issue as to whether the plaintiff's labeling was materially misleading. The Supreme Court heard oral argument on the petition on May 16, 1949. On the same day, the court denied the petition.

PRETRIAL PROCEEDINGS

A motion for a pretrial order to specify the issues to be tried was filed by the defendants with the 3-judge court. On June 14, 1949, the court entered the following statement of the issues:

ISSUES TO BE TRIED

"1. The constitutionality, under the due process clause of the Fifth Amendment to the Constitution as applied to the facts in this case, of that provision of Section 304 (a) of the Food, Drug, and Cosmetic Act under which the

defendants have taken the libel and seizure actions without affording to the plaintiff a hearing for the purpose of establishing that the plaintiff's labeling was not, in a material sense, misleading to the injury or damage of the purchaser or consumer.

2. Whether the defendants, in violation of the Fifth Amendment to the Constitution, acted arbitrarily, unlawfully, oppressively, and capriciously in determining, under Section 304 (a) of the Food, Drug, and Cosmetic Act, that the labeling of the plaintiff's product was, in a material respect, misleading to the injury or damage of the purchaser or consumer, without affording the plaintiff a hearing.'

Subsequent to June 14, 1949, answers were made to the plaintiff's request for admissions, to the plaintiff's written interrogatories, and to the defendants' written interrogatories.

TRIAL

Following the service of such answers, the case was tried before the threejudge court from October 17 to 27, 1949. At the conclusion of the trial, the court held in an oral decision that the particular provision of the law involved in the case relating to multiple seizures was unconstitutional and that the defendants, in initiating multiple libel proceedings against the plaintiff without first affording to them a hearing upon the issue of whether the labeling upon the plaintiff's product was misleading, acted arbitrarily, oppressively, and capriciously; and on December 14, 1949, the court handed down findings of fact and conclusions of law to that effect.

On the same day, December 14, the court entered a decree of permanent injunction against the defendants, pursuant to which the defendants were permanently enjoined from continuing or causing to continue the prosecution of any of the libel for condemnation actions pending against Nutrilite Food Supplement; and from instituting or causing to be instituted any further or additional libel for condemnation actions, or any other actions against Nutrilite Food Supplement, under the provisions of the Act which had been held to be unconstitutional.

APPEAL

The defendants appealed directly to the United States Supreme Court from the decision of the three-judge court. On May 29, 1950, the following opinion reversing such decision was handed down by the Supreme Court:

Mr. Justice Douglas: "This is an appeal from a three-judge District Court specially constituted on appellee's application for an injunction to restrain enforcement of a portion of an Act of Congress for repugnance to the Due Process Clause of the Fifth Amendment.2

"Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 334 (a), 52 Stat. 1044, as amended, 62 Stat. 382, 21 U. S. C. Supp. III § 334 (a), permits multiple seizures of misbranded articles 'when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.' 3

¹²⁸ U. S. C. §§ 1253, 2101, 62 Stat. 928, 961.
228 U. S. C. §§ 2282, 2284, 62 Stat. 968.
3 The provision of which the quoted portion is a part reads as follows: "Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505. be introduced into interstate commerce, that is also to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon

"Appellee is the exclusive national distributor of Nutrilite Food Supplement, an encapsulated concentrate of alfalfa, water cress, parsley, and synthetic vitamins combined in a package with mineral tablets. There is no claim that the ingredients of the preparation are harmful or dangerous to health. The sole claim is that the labeling was, to use the statutory words, 'misleading to the injury or damage of the purchaser or consumer' and that therefore the preparation was 'misbranded' when introduced into interstate commerce.

"This was indeed the administrative finding behind eleven seizures resulting in that number of libel suits, between September and December, 1948. The misbranding, it was found, resulted from the booklet which accompanied Shortly thereafter the present suit was instituted to have the preparation.4 the multiple seizure provision of § 304 (a) declared unconstitutional and to dismiss all libel cases except the first one instituted. The District Court held that appellants had acted arbitrarily and capriciously in violation of the Fifth Amendment in instituting multiple libel suits without first affording the appellee a hearing on the probable cause issue; that the multiple seizure provision of § 304 (a) was unconstitutional under the Due Process Clause of the Fifth Amendment; and that appellants should be permanently enjoined from instituting any action raising a claim that the booklet accompanying the preparation was a misbranding since it was not fraudulent, false, or misleading. 87 F. Supp. 650.

"First. The administrative finding of probable cause required by § 304 (a) is merely the statutory prerequisite to the bringing of the lawsuit. When the libels are filed the owner has an opportunity to appear as a claimant and to have a full hearing before the court. This hearing, we conclude, satisfies the

requirements of due process.

"At times a preliminary decision by an agency is a step in an administrative proceeding. We have repeatedly held that no hearing at the preliminary stage is required by due process so long as the requisite hearing is held before the final administrative order becomes effective. See Lichter v. United States, 334 U. S. 742; Inland Empire Council v. Millis, 325 U. S. 697; Opp Cotton Mills v. Administrator, 312 U.S. 126.

the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitation shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer."

misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer."

*The booklet, How to Get Well and Stay Well, is used by salesmen in soliciting prospective customers: A version of the booklet in use in 1947 represented that Nutrilite had "cured or greatly helped" such "common ailments" as "Low blood pressure, Ulcers, Mental depression, Pyorrhea, Muscular twitching, Rickets, Worry over small things, Tonsilitis, Hay Fever, Sensitiveness to noise, Underweight, Easily tired, Gas in Stomach, Cuts heal slowly, Faulty vision, Headache, Constipation, Anemia, Boils, Flabby tissues, Hysterical tendency, Eczema, Overweight, Faulty memory, Lack of ambition, Certain bone conditions. Nervousness, Nosebleed, Insomnia (sleeplessness), Allergies, Asthma, Restlessness, Bad skin color, Poor appetite, Biliousness, Neuritis, Night blindness, Migraine, High blood pressure, Sinus trouble, Lack of concentration, Dental caries, Irregular heartbeat, Colitis, Craving for sour foods, Arthritis (rheumatism), Neuralgia, Deafness, Subject to colds." This version is the basis for an indictment now pending in the Southern District of California charging Lee S. Mytinger and William S. Casselberry with the misbranding of Nutrilite in violation of the Federal Food, Drug, and Cosmetic Act.

After a hearing prior to the indictment, appellee revised the booklet. Direct curative claims were eliminated. But pages 41–52 of the revised booklet were devoted to case histories explaining that Nutrilite brought relief from such ailments as diabetes, feeble-mindedness, stomach, pains, sneezing and weeping. Appellant Crawford, Associate Commissioner of Food and Drugs, concluded that there was probable cause to believe and that he did believe that this version of the booklet was misleading. On September 28 and 30, 1948, he recommended seizures of Nutrilite shipments.

Appellee thereafter ordered its salesmen to remove pag

28 and 30, 1948, he recommended seizures of Nutrilite shipments.

Appellee thereafter ordered its salesmen to remove pages 37-58 which contained the case histories. The pages which remained pointed to the dangers and prevalence of illness, described the discovery of Nutrilite, and recommended the booklet to those who wanted to get well and stay well. On December 2, 1948, appellant Larrick, Assistant Commissioner of Food and Drugs, made a probable cause determination on these pages of the booklet and recommended seizure.

Six new pages were thereafter added to the booklet. On December 9, 1948, appellant Dunbar, Commissioner of Food and Drugs, made a probable cause determination on that version of the booklet and recommended further seizures.

§\$ 304 (b) provides in part: "The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury."

"But this case does not go as far. Here an administrative agency is merely determining whether a judicial proceeding should be instituted. Moreover, its finding of probable cause, while a necessary prerequisite to multiple seizures, has no effect in and of itself. All proceedings for the enforcement of the Act or to restrain violations of it must be brought by and in the name of the United States. § 307. Whether a suit will be instituted depends on the Attorney General, not on the administrative agency. He may or may not accept the agency's recommendation. If he does, seizures are made and libels are instituted. But the seizures and suits are dependent on the discretion of

the Attorney General. "It is said that these multiple seizure decisions of the administrator can cause irreparable damage to a business. And so they can. The impact of the initiation of judicial proceedings is often serious. Take the case of the grand jury. It returns an indictment against a man without a hearing. It does not determine his guilt; it only determines whether there is probable cause to believe he is guilty. But that determination is conclusive on the issue of probable cause. As a result the defendant can be arrested and held for trial. See Beavers v. Henkel, 194 U. S. 73, 85; Ex parte United States, 287 U. S. 241, 250. The impact of an indictment is on the reputation or liberty of a man. The same is true where a prosecutor files an information charging violations of the law. The harm to property and business can also be incalculable by the mere institution of proceedings. Yet it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts. Discretion of any official may be abused. Yet it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination. Phillips v. Commissioner, 283 U. S. 589, 596-597; Bowles v. Willingham, 321 U. S. 503, 520; Yakus v. United States, 321 U. S. 414, 442-443.

"One of the oldest examples is the summary destruction of property without prior notice or hearing for the protection of public health. There is no constitutional reason why Congress in the interests of consumer protection may not extend that area of control. It may conclude, as it did here, that public damage may result even from harmless articles if they are allowed to be sold as panaceas for man's ills. A requirement for a hearing, as a matter of constitutional right, does not arise merely because the danger of injury may be more apparent or immediate in the one case than in the other. For all we know the most damage may come from misleading or fraudulent labels. That is a decision for Congress, not for us. The decision of Congress was that the administrative determination to make multiple seizures should be made without We cannot say that due process requires one at that stage. a hearing.

"Second. The District Court had no jurisdiction to review the administrative

determination of probable cause.

"The determination of probable cause in and of itself had no binding legal consequence any more than did the final valuation made by the Interstate Commerce Commission in United States v. Los Angeles & S. L. R. Co., 273 U. S. 298. It took the exercise of discretion on the part of the Attorney General, as we have pointed out above, to bring it into play against appellee's business. Judicial review of such a preliminary step in a judicial proceeding is so

unique that we are not willing easily to infer that it exists.

"Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts.6 But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. Switchmen's Union v. Board, 320 U. S. 297, 305-306.

"The purpose of the multiple seizure provision is plain. It is to arrest the distribution of an article that is dangerous, or whose labeling is fraudulent

⁶ Review of an order of the Administrator refusing to permit an application for a new drug to become effective or suspending the effectiveness of an application is authorized in §505 (h), 21 U.S. C. §355 (h). Orders of the Administrator in connection with issuing, amending, or repealing regulations under §§401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, 604 are expressly made reviewable by §701 (e) and (f), 21 U.S. C. §371 (e) and (f).

or misleading, pending a determination of the issue of adulteration or misbranding. The public therefore has a stake in the jurisdictional issue before us. If the District Court can step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case, the public will be denied the speedy protection which Congress provided by multiple seizures. It is not enough to say that the vitamin preparation in the present case is not dangerous to health. This preparation may be relatively innocuous. But the statutory scheme treats every 'misbranded article' the same in this respect—whether it is 'dangerous to health,' or its labeling is 'fraudulent,' or materially 'misleading to the injury or damage of the purchaser or consumer.' What we do today determines the jurisdiction of the District Court in all the cases in that category. If the court in the present case can halt all multiple seizures but one, so can the court in other cases. The means which Congress provided to protect consumers against the injurious consequences of protracted proceedings would then be seriously impaired. Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures. We would impair or destroy the effectiveness of that device if we sanctioned the interference which a grant of jurisdiction to the District Court would entail. Multiple seizures are the means of protection afforded the public. Consolidation of all the libel suits so that one trial may be had 8 is the relief afforded the distributors of the articles.

'Reversed.

"Mr. Justice Burton concurs in the result.

"Mr. Justice Clark took no part in the consideration or decision of this case."

Mr. JUSTICE JACKSON (dissenting): "The Court does not deal at all with what appears to be the ultimate issue decided by the court below.

"The trial court of three judges wrote no opinion but made forty-three detailed findings of fact which would require twenty of these printed pages to reproduce and which summarize a 1,500-page record of a long trial. Those findings are made largely on undisputed evidence and on evidence from government sources. This Court does not criticize or reverse any of them.

"The substance of these is to find that the Government instituted a multiplicity of court actions, with seizures in widely separated parts of the country, with a purpose to harass appellee and its dealers and intending that these actions and the attendant publicity would injure appellee's business before any of the issues in such cases could be tried. This, the court held, was justified by no emergency the product being, at worst, harmless and having been marketed for years with knowledge of the Department.

"Assuming as I do that the Act on its face is not constitutionally defective, the question remains whether it has been so misused by refusal of administrative hearing, together with such irreparable injury in anticipation of judicial hearing, as to deny appellee due process of law or to amount to an abuse of process of the courts.

"The Government has sought and received from this Court protection against a multiplicity of suits under circumstances where injury was less apparent than in this. Landis v. North American Co., 299 U. S. 248. The holding of the court below and the contention of the appellee here that the

The search of the content of the con

Government is not entitled to so apply the statute as to bring multiple actions designed to destroy a business before it can be heard in its own defense is not frivolous, to say the least.

"I am constrained to withhold assent to a decision that passes in silence

what I think presents a serious issue.'

Mr. Justice Frankfurter (dissenting): "While I agree with the Court as to the constitutional and statutory issues canvassed in its opinion, I am unable to answer Mr. Justice Jackson's dissent, and I must therefore yield to it.

"Of course Congress may constitutionally vest judicially unreviewable discretion in an executive agency to initiate multiple suits in order to stop trafficking in pernicious drugs or even in those that are harmless, where efficacy is misrepresented. I agree that it has done so in the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040, 21 U. S. C. § 301 et seq. But it does not at all follow that Congress has thereby cut off the right of access to the courts to prove that the enforcing agency has not acted within the broadest bounds of fair discretion, rare as the occasion may be for such an attempt and however improbable its success.

"Such I understand to be the nature of the proceedings below and such the basis of the District Court's decree. Unless we can say, as I cannot, that the findings in support of it have no support in the evidence, we should not hold that the court below was without jurisdiction to entertain the suit.

"The limited claim which the District Court sustained falls precisely within the qualification left open by this Court in a leading case sustaining the power of Congress to vest unreviewable discretion in executive agencies. When the Court was urged to deny this power of Congress and 'extreme cases' were put showing 'how reckless and arbitrary might be the action of Executive officers,' the Court made this answer:

It will be time enough to deal with such cases, as and when they arise. Suffice it to say, that the courts have rarely, if ever, felt themselves so restrained by technical rules that they could not find some remedy, consistent with the law, for acts, whether done by government or by individual persons, that violated natural justice or were hostile to the fundamental principles devised for the protection of the essential rights of property. *Monongahela Bridge Co.* v. *United States*, 216 U. S. 177, 195.

Mr. Justice Harlan, speaking for the Court, cast its thought in the language current at the time. But the thought behind the words is not outmoded and controls, I believe, the case before us."

The plaintiff filed a petition for rehearing in the Supreme Court, together with a motion for a stay of the mandate. On June 14, 1950, Mr. Justice Douglas denied the motion for a stay of the mandate. A motion was filed in the District Court on July 5, 1950, to stay the entry of an order on the mandate in that court until the Supreme Court had had an opportunity to act upon the petition for rehearing. On July 21, 1950, Judge Tamm denied the motion for a stay and, in compliance with the mandate of the Supreme Court, ordered that the decree of permanent injunction of December 14, 1949, be dissolved and vacated. A petition to the three-judge court to review Judge Tamm's action was filed on behalf of the plaintiff on July 22, 1950. On October 16, 1950, the Supreme Court denied the petition for rehearing. On November 15, 1950, the three-judge court entered an order denying the petition for review of Judge Tamm's action.

3383. Action to enjoin and restrain interstate shipment of Nutrilite Food Supplement. U. S. v. Mytinger & Casselberry, Inc., Nutrilite Products, Inc., Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg. Consent decree granting injunction. (Inj. No. 214.)

COMPLAINTS FILED: The original complaint was filed on September 22, 1949. On October 23, 1950, the following amended complaint was filed:

"The United States of America, plaintiff herein, by and through Ernest A. Tolin, United States Attorney for the Southern District of California, Central Division, files this Amended Complaint for Injunction and respectfully represents unto the Honorable Court as follows:

"1. This proceeding is brought under section 302 (a) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 332 (a)], hereinafter referred to as 'the Act,' specifically investing the several United States District Courts with jurisdiction to enjoin and restrain violations of section 301 of said Act [21]

U. S. C. 331] as hereinafter more fully appears.

"2. The defendants, Nutrilite Products, Inc., a California corporation having its principal place of business at Buena Park, California, and Carl F. Rehnborg, an individual who resides at Buena Park, California, are the manufacturers and packers of an article of drug designated by name as Nutrilite Food Supplement. The defendants, Mytinger & Casselberry, Inc., a California corporation having its principal place of business at Long Beach, California, and Lee S. Mytinger and William S. Casselberry, individuals residing at Long Beach,

California, are the exclusive national distributors of the drug.

"3. 'Nutrilite Food Supplement' is prepared and distributed in three dosage forms designated as 'Nutrilite Food Supplement XX,' 'Nutrilite Food Supplement X,' and 'Nutrilite Food Supplement Junior.' Each is comprised of an encapsulated multi-vitamin preparation with a base of an extract of alfalfa, dried watercress, and dried parsley, combined in a package with multi-mineral and vitamin tablets. Nutrilite XX and Nutrilite X differ in the package content of vitamin capsules; Nutrilite XX contains 62 capsules, two per day are recommended, and the price is \$19.50 per package, whereas Nutrilite X contains 31 capsules, one per day is recommended, and the cost is \$12.00 per package. Nutrilite Junior also contains 31 capsules, one per day is recommended, the price is \$7.50 per package, and it differs from Nutrilite X in that the potency of Vitamins A, D, and B₁ in each capsule is one-half that of each capsule of Nutrilite X.

"4. The label of the drug 'Nutrilite Food Supplement XX' is, in part, as

follows:

[Front Panel]

The nutrilite base is a highly concentrated extract of specially grown alfalfa and selected watercress and parsley, processed by methods known only to nutrilite chemists, and obtainable only in nutrilite products. To the base are added crystalline vitamins and vitamin concentrates.

This package contains multiple vitamin capsules and mineral tablets.

Suggested Use: One capsule and three tablets twice daily.

Two capsules and six tablets supply the following amounts and proportions of minmum daily adult requirements:

Vitamin A	25, 000	USP Units	625%	Calcium	950	Mgs.	125%
Vitamin D	2, 500	USP Units	625%	Phosphorus	562	Mgs.	75%
Vitamin B ₁	20	Mgs.	2000%	Iodine	0. 4	Mgs.	400%
Vitamin B ₂	10	Mgs.	500%	Iron	20	Mgs.	200%
Vitamin C	200	Mgs.	666%	Copper	2	Mgs.	XX
Vitamin B ₆	4	Mgs.	X	Manganese	2	Mgs.	x
Vitamin K	1	Mg.	xx	Zinc	2	Mgs.	x
Vitamin E	10	Int. Units	x	Cobalt	0. 2	Mgs.	x
Inositol	20	Mgs.	X	Nickel	0. 2	Mgs.	x
Folic Acid	1	Mg.	X	Fluorine	0. 2	Mgs.	x
Rutin	1	Mg.	·x	Niacinamide	25	Mgs.	XX
Para-aminobenz	oic 20	Mg.	X	Pantothenic	8	Mgs.	x
Acid				Acid			

(x) Need in human nutrition not established — (xx) Requirement not established.

The labels on Nutrilite X and Nutrilite Junior suggest one capsule and six tablets daily, and the statements of amounts of vitamins and minerals supplied correspond to that dosage. Recent shipments of Nutrilite XX bear labeling which represents that it contains in addition to the ingredients listed above 5 micrograms of Vitamin B₁₂ and 20 micrograms of Biotin in two capsules

(the recommended daily intake).

"5. The drug is not marketed through customary retail channels but is sold by distributors who directly solicit consumers to obtain written contracts (called programs) for delivery of one package of Nutrilite each month. These distributors, who also are purchasers of Nutrilite, are sponsored by other distributors in the defendant Mytinger & Casselberry, Inc. organization who are called 'potentate,' 'high potentate,' or 'exalted potentate' according to the volume of sales produced by his sponsored group.

"6. The distributors in the past have used and at the present time use numerous items of written, printed and graphic matter supplied by the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry in their distributional scheme.

"7. One item of such written, printed and graphic matter is a booklet entitled 'How to Get Well and Stay Well.' Distributors use and have used this booklet upon their initial approach to prospective consumers. The booklet, which discusses the relationship between vitamins, nutrition and disease, is left with the prospective purchaser for perusal at his leisure and is picked up by the distributor at the time he undertakes to complete the sale. booklet has been through at least four revisions, each precipitated by governmental action, but the defendant Mytinger and Casselberry, Inc., has contended each time that the earlier booklet made no false or misleading claims

for Nutrilite Food Supplement.

"8. The edition of 'How to Get Well and Stay Well' in use until May 1948 represented without qualification that Nutrilite is an effective therapeutic agent in 'almost every case' and is a cure of 'common ailments,' among which the following were specifically listed: low blood pressure, ulcers, mental depression, pyorrhea, muscular twitching, worry over small things, tonsilitis, hay fever, sensitiveness to noise, easily tired, gas in stomach, faulty vision, headache, constipation, boils, lack of ambition, nervousness, nosebleed, insomnia, (sleeplessness), allergies, asthma, restlessness, bad skin color, biliousness, migraine, high blood pressure, sinus trouble, lack of concentration, dental caries, irregular heartbeat, flabby tissues, hysterical tendency, eczema, overweight, faulty memory, colitis, craving for sour foods, arthritis (rheumatism), neuralgia, deafness, subject to colds. At another point the booklet implied that 'cancer, diabetes, heart trouble, high blood pressure, constipation, tuberculosis, arthritis, neuritis' and numerous other diseases would respond to Nutrilite treatment. This booklet also contained testimonial letters by means of which the drug Nutrilite was represented as an effective treatment for many diseases. Said representations were false and misleading in that Nutrilite is not effective in the treatment and cure of such conditions and diseases.

"9. After the firm had been given an opportunity to show cause why a contemplated criminal proceeding should not be instituted against it, it undertook a revision of the booklet. Acting upon the advice of an attorney that they should eliminate the names of all diseases and use instead descriptions of symptoms manifested by persons who had sought relief through Nutrilite, the defendant Mytinger & Casselberry, Inc., devised a 58-page edition of 'How to Get Well and Stay Well.' The principal effects of revision were the elimination of specific disease names, but this edition included a number of case histories explaining to the prospective purchaser how other persons had obtained relief and freedom from such ailments and symptoms of disease as: low vitality, over-fatigue, insomnia, poor appetite, gastro-intestinal distress, recurrent vague aches and pains, weak eyes, defective teeth, nervousness, heart disease, stomach pains, disease conditions requiring surgery, feeble-mindedness, diabetes, hemorrhage connected with the menopause, indigestion, sneezing, weeping, anemia, leukemia, sinus trouble, constipation, tuberculosis, headache, dizziness, vomiting, and all deficiency diseases.

"In order to convey to the public the false and misleading impression that Nutrilite Food Supplement will cure every ailment and disease afflicting mankind, and yet avoid mentioning any specific disease names, the defendants Mytinger & Casselberry, and Lee S. Mytinger and William S. Casselberry, with this revision, inaugurated a subterfuge which they call a 'new language.'

In the 'new language' every ailment or illness is referred to as a state of 'non-health.' This unhappy state is claimed to be a result of body chemical imbalance. When the body is in 'chemical balance,' it is said to be free from all illness and in a state of health. The use of Nutrilite Food Supplement is claimed to bring the body into chemical balance, and thus to bring about the condition of health. The 'new language' insists that Nutrilite will cure nothing—the patient merely gets 'well through the use of Nutrilite.

"Examples of this, found in the 58-page booklet, follow:

Page 30 - Your body is a chemical machine, and always the chemical balance must be maintained. When your body gets out of chemical balance, you are ill. When you get into chemical balance and stay there, you are well.

Page 40 - Remember that NUTRILITE never cures anything. NUTRILITE provides the body with needed nutrilites and other vital micro-food factors. The body takes these and rebuilds. In the process of rebuilding, the inner cause of the deficiency ailment disappears, and consequently the symptoms cease to bother. Then the person is well, and he got well through the use of NUTRILITE, but nothing was cured.

"The 'Sales Manual,' authored and distributed by defendants Mytinger & Casselberry, instructs their salesmen in the use of the 'new language,' in passages such as the following:

Pages 30, 30 - You should capitalize on this new approach and lean over backwards to keep away from the medical procedure. Stay in this newer field. which is the adjustment, through the use of a food supplement, of chemical imbalance resulting from vitamin-mineral deficiency.

Pages 30, 31 - WE NUTRILITE DISTRIBUTORS NEED TO THINK ONLY IN TERMS OF HEALTH AND NOT-HEALTH, and We should FORGET ALL ABOUT PARTICULAR AIL-MENTS AND THEIR MEDICAL NAMES. FOR THE COMMON CONCEPTION OF SPECIFIC AILMENTS WITH MEDICAL NAMES, WE MUST SUBSTITUTE IDEAS OF FULL NUTRITION, CHEMICAL BALANCE AND HEALTH.

"When the 58-page edition of the booklet became involved in litigation arising under the Federal Food, Drug, and Comestic Act, the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, made further revisions by eliminating the case histories and by substituting new pages. the final result of which was a 42-page edition of the booklet.

"10. The 42-page edition of 'How to Get Well and Stay Well,' when read as a whole, as well as through specific claims, conveys to the reader the false and

misleading impression that:

(a) Almost everyone in the United States is either ill or about to become ill:

(b) Almost every common illness including those most responsible for

premature death is due to vitamin deficiencies;
(c) The average American diet is deficient in certain vital food factors, including both known and unknown vitamins and minerals which are

called 'nutrilites' by all chemists; (d) These dietary deficiencies are attributable to depleted soil, processing practices and storage methods which make it impossible to obtain in the diet the food factors that are essential to health;

(e) That the common illnesses may be prevented and cured through putting these food factors into the body to bring it into chemical balance;

(f) Illness is merely the result of chemical imbalance, and health is the

result of chemical balance; and

(g) Chemical balance and thus getting well and staying well may be achieved through the use of Nutrilite which contains not only the known vitamins and minerals but also, because of its secret and concentrate base, the unknown vitamins and minerals.

"11. Some typical statements used to develop these impressions in the 42page edition of the booklet 'How to Get Well and Stay Well' as as follows: Foreword: What we have tried to do in this book is show the average American, ill with the usual American deficiency ailments in the customary chronic manner, what may be the cause of his illness, and how he should proceed to get well and stay well.

Page 6 - Your study of yourself, the members of your family, your relatives and friends has shown you that almost *everyone* is more or less ill.

Page 10 - . . . The result is that almost all members of our families have bodies which are malnourished, and show evidences of the malnutrition which causes most of our common deficiency ailments.

So the purpose of this book—and the objective of the person who lent you this book—is to bring you to the point where you will recognize the fact clearly that your illness and the illness of your family is, in almost every case, the result of a failure to supply your body and the bodies of the members of your family with the vital food factors.

Page 11 - And remember your reward—a good chance for the relief of deficiency ailments if you have any (and most of our current and common ailments result from deficiencies) and their prevention if you are now lucky enough to be free from them.

Page 22 - Now, be sure to remember this: the American diet is deficient in nutrilites, the protective food factors. Why is this true? Why are we sick and ailing in this land of plenty? Why don't we get all the vitamins and minerals need?

Page 23 - English Academy of Medicine, lancet, states: "99% of common illnesses are due to or are superimposed on vitamin deficiencies."

Page 28 – The flat wheel you develop as a result of diet deficiencies may show itself as one of the common or not so common deficiency diseases, including those most responsible for death in our 40's and 50's, whereas we *should* live in good health and vigor, and with full possession of our faculties, to the age of 90 or 100.

. . . Most of the ills and diseases of human beings are unnecessary—they are the result of chemical starvation of our bodies for substances vitally necessary to life.

Page 33 - According to a recent study made by a large and well-known eastern college, only one in a thousand is not suffering from deficiency—from malnutrition. This means that no one can safely say: "I am perfectly healthy and my body is sound and well nourished."

Think of our population, and think of all the common ailments. Pick up any newspaper and you read of prominent citizens dying in early middle age of the various diseases that claim the lives of so many. Think of the people you know who are ill right now, and suffering, without relief.

This would certainly make it look as though each of us might have a body containing many imitation bricks, so that we look reasonably well, we can get around and do some work, but either we are now experiencing some deficiency disease, or we are ready to come down with one.

Page 40 – The sufferer with dietary deficiencies and deficiency ailments has the problem of getting into his body all the basic food factors which either were never in his food to start with or which have been partially removed in some way. If you are such a sufferer, how can these basic food factors be added to your food? We believe that NUTRILITE Food Supplement is at least one answer.

The man, woman or child who is reasonably well, and who wishes to stay that way and if possible improve, has also the problem of keeping his body supplied with all the vital food factors. If you are in this group you too have a problem, in this civilized age of devitalized and imitation food. And here again, you can turn to—NUTRILITE Food Supplement.

"12. Notwithstanding the effort by defendants Mytinger & Casselberry, Inc., Lee S. Mytinger and William S. Casselberry to avoid mention of diseases by name, the 42-page edition of 'How to Get Well and Stay Well' refers to a number of specific diseases, symptoms and conditions for which the product Nutrilite Food Supplement is offered as a preventive, treatment and cure:

Page 1 - Weak and lacking in energy; trouble digesting food; stomach pains; decaying teeth; trouble with heart and other important organs; aches, pains and discomfort in various parts of the body;

Page 2 - Difficulty seeing, hearing;

Page 3 — Partial inability to move the various parts of the body, (stroke or paralysis); partial breakdown of the thought processes (confused thinking); difficulty seeing, hearing, or failure of other sense organs; extreme personality changes; any illness, breakdown or invalidism; any weakness or incapacitated body racked with aches and pains:

Pages 5, 6 - Tuberculosis; spinal curvature;

Page 30 - Allergies;

Page 35 - Old age;

Page 38 - Psychological disturbances.

In addition the booklet, at page 3, represents and suggests that Nutrilite Food Supplement will nourish and rebuild the brain, the heart and the glands. These statements, claims, and representations are false and misleading.

"13. In addition to the statements referred to in paragraphs 11 and 12, there are many instances in the booklet in which defendants Mytinger & Casselberry. Inc., and Lee S. Mytinger and William S. Casselberry, have attempted to fortify certain false claims by use of 'facts' which are inaccurately presented and from which the defendants draw false and misleading conclusions. First, on pages 3 and 4 there is a fragmentary and incomplete quotation from a New York Times article for June 29, 1945, which indicates a rather high rejection rate for women applying for the W. A. C. The booklet 'How to Get Well and Stay Well' attributes these rejections to vitamin and mineral deficiencies, despite the fact that the complete New York Times article lists the specific causes of such rejection, and vitamin and mineral deficiencies are not included. Second, on page 4 there appears a statement that a survey by a large eastern college showed that only 2 out of 2,511 persons studied in Pennsylvania were receiving the vitamins, minerals and proteins they needed. The official report of that survey does not support this claim. Third, on page 6 appears the statement that 32% of draftees in World War II were rejected and that 52½% had some disability. These statements are presented in a context to force the reader to conclude that these rejections and disabilities were the result of vitamin and mineral deficiencies. Official selective service statistics show that vitamin and mineral deficiencies accounted for a negligible percentage of such rejection.

"Fourth, on pages 7, 8, and 9 false statements are made that Carl Rehnborg, the discoverer of Nutrilite, 'majored in blochemistry in an eastern university'; that he 'specialized in the chemistry of foods'; that he took part in 'early vitamin research experiments'; and that he 'returned to the United States in 1927' and 'began a six-year period of intensive study and experimentation.'

"14. Though the defendants, Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry assert that the interstate distribution of the booklet 'How to Get Well and Stay Well' has been discontinued, the booklet remains in the hands of distributors who use it in their sales presentation. Even this alleged discontinuance of interstate distribution was made with the assertion that use of the booklet did not violate the Federal Food, Drug, and Cosmetic Act.

"15. In addition to the booklet 'How to Get Well and Stay Well,' the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Cassel-

berry, have distributed and now distribute and have caused to be distributed to the sales force of Mytinger & Casselberry, Inc., certain other written, printed, and graphic matter consisting of a booklet entitled 'Sales Manual-Nutrilite Food Supplement,' a book entitled 'The National Malnutrition' by D. T. Quigley, a book entitled 'Man Alive, You're Half Dead!' by Daniel C. Munro (New York, 1950), weekly issues of a sales publication entitled 'Nutrilite News,' and various reprints from popular publications including but not limited to the following:

'Modern Miracle Men' by Rex Beach, S. Doc. No. 264, 74th Cong., 2d sess. (1941).

'We Feed our Hogs Better than our Children' by Fred Bailey, American Magazine (October 1947).

'Nutrition and Pregnancy' by Bruce Bliven, reprinted from Ladies' Home Journal (November 1947).

'The Miracle of Dr. Spies' by Dickson Hartwell, reprinted from Colliers (January 31, 1948).

'Vitamins are not Drugs!' by Dr. Simon Bensen, reprinted from *The Apothecary* (June 1946), by Lee Foundation for Nutritional Research. 'The Latest on Vitamin Pills' by Clarence Woodbury, Woman's Home

Companion (January 1949). 'What Makes You Healthy?' by Winifred Raushenbush, Ladies' Home

Journal (March 1949). 'Bangs Disease and Undulant Fever are Due to Nutritional Deficiencies' by J. F. Wischhusen, American Feed and Grain Dealer, Minneapolis, Minnesota (July 1948).

'A Practical Way to Avoid Malnutrition' by Royal S. Lee, Lecture Delivered at American Academy of Applied Nutrition reprinted by Lee Foundation for Nutritional Research (April 17, 1948).

'Are We Starving to Death' by Neil M. Clark, reprinted from Saturday Evening Post (1945).

'Soil, A Foundation of Health' by Arnold P. Yerkes, International Har-

vester Co. (Chicago, 1946). 'Cancer, a Nutritional Deficiency' by J. R. Davidson, reprinted from Question Mark (February 1943). 'Uncle Sam Against Cancer.'

-for Heart Disease: Vitamin E' by J. D. Ratcliff, reprinted from Coronet (October 1948).

'How to Get Well and Stay Well' reprinted from General Church Edition, 'Health is on the Downgrade' by Henry Trautman, M. D. reprinted from Life Today (December 1949).

"Food" for Thought' by Rev. Henry Retzek, reprinted from Priest Magazine (December 1945).

'The Prevention of Recurrence in Peptic Ulcer' by D. T. Quigley, Lee Foundation for Nutritional Research.

'The Need for Vitamins' by L. Stambovsky, Lee Foundation for Nutritional Research.

'Talking about Food' by George Tyner, reprinted from Journal of the American Academy of Applied Nutrition (Autumn, 1947).

'You Can't Build a Live Body with Dead Food.'

'Why Should You Use Nutrilite?'

'Living Should be Fun' by Carlton Fredericks. (Institute of Nutrition Research, Inc.)

The said defendants also supply the sales force with a number of motionpictures, including but not limited to the following:

> American Living with Nutrilite On the Other Side of the Fence Hidden Hunger Strange Hunger Hunger Signs

and with recorded 'sales presentations.'

"16. The said written, printed and graphic matter is used in the defendants' scheme of marketing said articles of drugs for the purposes of educating the distributors (who also are users of the article of drug) as to the conditions for which 'Nutrilite Food Supplement' is claimed to be useful and for the purpose of supplying these distributors with information and material that they may employ in educating the prospective customers as to their probable need for 'Nutrilite Food Supplement.' The 'Sales Manual' directs that salesmen read and study the material referred to in paragraph 15 in order to learn about vitamins and minerals and the benefits that vitamins and minerals generally, and 'Nutrilite Food Supplement' specifically, will accomplish. The distributors are instructed to quote from 'The National Malnutrition' by D. T. Quigley to bring the prospective customer to the realization that he is malnourished and that his ailments, whatever they may be, are due to malnutrition which 'Nutrilite Food Supplement' will correct. The news letter 'Nutrilite News' suggests that the book 'Man Alive, You're Half Dead!' by Daniel C. Munro and the various reprints and motion pictures referred to in paragraph 15 be obtained through Mytinger & Casselberry, Inc., at reduced rates and placed in the hands of, or shown to, prospective purchasers of 'Nutrilite Food Supplement' and that the statements in such written, printed, and graphic matter be used as 'ammunition' in sales presentations, all for the purpose of inducing sales of 'Nutrilite Food Supplement.'

"The films referred to in paragraph 15, when taken as a whole, emphasize the impoverishment of soil and its effect on the nutritive content of plants, and this is claimed to result in improper diets in humans leading to illnesses and malformations. 'American Living with Nutrilite' portrays Nutrilite Food Supplement as the best solution to the problem of widespread malnutrition which is graphically presented in the other films. Typically, the distributor calls on the potential customer and makes a sales presentation in which 'Nutrilite Food Supplement' is offered as an effective agent for the prevention and cure of 'ill-health' or 'chemical imbalance.' This presentation is documented by quotations from the written, printed, and graphic matter specified above. The distributor is encouraged to, and does, make use of testimonials obtained locally. He relates to the prospective customer the details of miraculous improvements' in the health of persons living in the community that are claimed to have resulted from 'Nutrilite Food Supplement.' This presentation includes representations that 'Nutrilite Food Supplement' has been effective in the treatment of cancer, heart disease, ulcers, arthritis, tuberculosis, spastic colitis, Parkinson's disease—to name only a few. The distributor points to passages in the written, printed, and graphic matter to show that almost every disease and ailment known to mankind is due to a deficiency of vitamins and minerals and that vitamins and minerals will be an adequate treatment, preventive and cure of such diseases and ailments.

"17. In the setting in which they are used, the books 'The National Malnutrition' by D. T. Quigley and 'Man Alive, You're Half Dead' by Daniel C. Munro represent and suggest that all of the symptoms, conditions and diseases which beset the human body result from dietary deficiencies and that, excepting accidental injuries, all such symptoms, conditions and diseases can be prevented and adequately treated by the use of 'Nutrilite Food Supplement,' which said representations and suggestions are false and misleading.

"18. Typical of these false and misleading representations are:

'The National Malnutrition' by D. T. Quigley (Lee Foundation for Nutritional Research)— $\,$

Page 1 - In the life of the ordinary person, the most common disease-producing factors are from food deficiencies.

Page 3 — Coincident with the introduction of these foods [marmalade and other sweets, candies, cookies, and products made with white flour and sugar], the school children [of the Outer Hebrides] showed a large incidence of tooth decay, adenoids, diseased tonsils, arthritis, tuberculosis, and other diseases that go with deficiency diets. The people in the back part of the Island of Lewis and the people of the other islands who were not exposed to the diets of the more highly civilized English and Scotch suffered no deficiency disease. They continued to live to be near one hundred years of age without tuberculosis, arthritis, heart disease, diseases of digestion, or tooth decay.

Page 7 - We have been afflicted by mass diseases for so many decades that the average layman and the average doctor, and quite obviously the average dentist, does not know what is normal.

Page 12 - No one vitamin prevents old age.

Page 13 - Only by a judicious combination of all vitamins, combined with sufficient minerals, do we have the answer to the problem of old age.

Page 30 — The small child on a deficient diet becomes afflicted with chronic tonsilitis. The school child may develop tuberculosis. The youth is pimply and anemic. All have bad teeth. Many have permanently crippled hearts due to rheumatic infections. Seventy percent have rickets. A large proportion have digestive diseases and constipation. All these handicaps are the results of errors in diet.

Page 36 - Clinical tests on the nutrition of persons suffering neuroses, irritability and other forms of nerve and mental disease show that a great number of them may be improved by taking nicotinic acid, which is considered the specific treatment for pellagra. This indicates that many cases of insanity are on a deficiency basis, and that the persons who are insane from pellagra are not the only group suffering insanity because of inadequate diet.

Page 41 - Perhaps the most common infections are those connected with the upper respiratory tract—the diseases ordinarily known as colds, grippe, flu, and pneumonia. These diseases are largely diseases of the human animal, and undoubtedly affect humans because of the difference between human and animal diets.

Page 43 — The chronic gastritis and hyperacidity and stomach and duodenal ulcers are deficiency diseases the same as scurvy, beriberi, and rickets, and may be cured just as certainly and just as permanently by diet and proper mineral and vitamin intake.

Page 46 - Arthritis is undoubtedly due to infection built up on a deficiency basis, and may or may not have some connection with virus diseases . . .

Disease of the brain is well known to result from food deficiencies as in the case of the insanity accompanying pellagra. The insanities following attacks of flu, and the insanities which have been known to be cured after the removal of abscessed teeth are low grade brain infections which have been made possible by nutritional deficiency.

Page 49 - The evil effects of vitamin and mineral deficiencies here depicted, involving as they do diseases of the digestive organs, lung, heart, brain, and blood vessels, present a truly depressing picture.

Page 54 - A study of the requirements for normal nutrition and a study as to how well the average dietary meets these requirements leads to the conclusion that the average diet of the average civilized person of the present time is a deficient diet.

Page 55.— The largest diseased group in school children in the grade schools is that group which have severe colds, rheumatic fever, and rheumatic heart disease. In the high school group, the greatest disease producer is tuberculosis. The heart disease victim is the victim of some chronic focal infection. The victim of tuberculosis is also a victim of lowered resistance against disease, due to dietary deficiency. The problem of these diseased children is simply a problem of right and proper diet.

Page 67 - On the clinical side, many internists and some surgeons have come to consider vitamin C as a cure for stomach ulcers. Here they are recognizing a truth, but only a part of the whole truth—lack of vitamin C is undoubtedly one of the predominant causes of stomach ulcer (and stomach cancer). A complete treatment would mean a treatment with all other vitamins and minerals lacking in the individual's diet, as well as with Vitamin C.

Page 76 - The change that might be brought about by the adoption of scientific diet would be a very spectacular and decided change. Somewhere from 70 to 80 per cent of the disease that now afflicts the human animal would be eliminated. The average age of the average human being could be extended from somewhere around sixty to well over one hundred years.

Page 82 - Stomach or duodinal [sic] ulcer is as surely a dietary deficiency disease as is scurvy or pellagra.

Page 86 – That the doctors suffer equally with the lay public in deficiency diseases is quite evident. Mortality records show that doctors die from heart and blood vessel diseases in as great numbers as does the general population. The average doctor has as much pyorrhea and tooth decay as the average layman. The average doctor is as often crippled by neuritis and arthritis and has as much appendicitis, gall bladder disease, stomach ulcer and cancer as the layman. The need for educating doctors is very great. The reception of new ideas such as these is slow in the medical profession.

Page 96 - The great mass of people suffering from digestive disorders, heart symptoms, rheumatic pains and aches, and fatigue will notice improved health conditions very soon after the beginning of such a regime.

Pages 100, 101 - Then comes the school period with its sinus disease, children's febrile diseases and tonsilitis. The major part of the school child's diet is composed of refined carbohydrates, sugar and white flour. Remove them from the diet, and the incidence of sinus disease and tonsilitis will decrease to the vanishing point. Putrid tonsils and rotten teeth are logically removed. The cause is left. The result is a child who will grow to adulthood accumulating the usual mass of such diseases as Tuberculosis, Rheumatic Fever, Peptic ulcers, Heart diseases, susceptibility to every infection that comes along, fatigability—ALL CONDITIONS WHICH WOULD BE NON-EXISTENT IF THE DIET WERE CORRECT.

There are a number of mental and nervous diseases which can be treated successfully by adequate attention to nutrition. Even the treatment of venereal disease can be improved and painful conditions like arthritis and neuritis are more successfully treated if nutrition is made a first consideration.

'Man Alive, You're Half Dead!' by Daniel C. Munro (New York, 1950)—

Page 4 - The research of selfless scientists, who have devoted their lives to the banishment of disease, has demonstrated that much of this ill-being is due to wrong eating;

Page 14 - Directly and definitely, according to modern scientific findings, vitamin and mineral deficiencies have a specific bearing upon these great afflictions that beset mankind:

The common cold, pneumonia and other respiratory diseases; ulcers of the stomach, the duodenum and the intestine; heart trouble and hardening of the arteries; headaches; goitre; colitis (the general term for inflammation of the colon); deafness and the degenerative diseases of middle age; prostatic disturbances in men; uterine disturbances in women, and many others.

Page 17 — Every reader of this book can doubtless name many friends and acquaintances who have died of thrombosis, angina, cerebral hemorrhage (stroke), and kindred diseases—most of them the dreadful results of starvation—not a lack of food in *quantity*, but starvation of some essential food element.

Page 25 - Appendicitis, on final analysis, is a deficiency disease, infection appearing only after deficiencies in the diet have caused degeneration.

Page 26 - If you are below par, suffer from indigestion, frequent colds and other minor ailments, the information contained in the pages which follow may point the way to the banishment of all these ills.

If you wish to forestall those chronic diseases which make old age unhappy, often prematurely, and wish to live so that your fifties and sixties will be your age of major opportunities in business and social activities, you will find in these pages information of the utmost importance.

Page 40 – The idea of taking tablets or capsules to supplement your diet may seem strange to you who are in apparent good health. Actually it is the soundest kind of health insurance. If you really are not deficient in food fatcors, (but I believe all adults *are* deficient) such procedure will do you no harm whatever.

Page 42 - There is a definite correlation between a moderate diet (which however *must* contain all the necessary food factors) and longevity.

Page 85 — Gall bladder disease, ulcers of the stomach and intestine, pyelitis, colitis or degenerative disease of the heart and blood vessels, all are, in the primary stage, deficiency diseases. The best protection against such diseases is obtained by adequate intake of all the nutritional factors which produce perfect balance and metabolism.

Page 86 - There is a group of diseases striking with deadly effect among middle-aged and older people where the deficiency of Vitamin A plays an important part.

One of them is the heart disease, coronary thrombosis, in which a thrombus or clot forms in the coronary artery, one of the arteries that supply the heart muscles with nutrition in the form of blood.

I have no doubt that one reason for our being an eyeglass wearing nation is a deficiency of Vitamin A.

Pages 100, 101 - I am convinced that many of our mental diseases are deficiency diseases.

Let me here call attention to the similarity in the pathology (tissue degeneration) of three distinct disease entities.

Spastic colitis.

Angina Pectoris.

Migraine headache.

In spastic colitis there is a spastic contraction of a tube of involuntary muscle—the colon.

In angina pectoris there is a spastic contraction of a tube of involuntary muscle—the coronary artery, supplying blood to the heart muscle itself. In migraine headache there is a spastic contraction of a tube of involuntary muscle—an artery wall in the brain.

In these three cases the essence of the pathology is the same—a disturbance of the nerve muscle relationship. These are typical cases of deficiency of Vitamin B Complex. Angina pectoris is much more serious than the other two because it affects a vital part, the heart.

. . . The Vitamin B Complex deficiency is even more important in producing heart degenerative disease I believe that this is the underlying story of the sudden deaths in middle life of so many of our prominent business men!

Nicotinic acid, one of the chemically isolated fractions of Vitamin B, has given wonderful results, in recent studies, in curing psychosis and mental

disease. Still another study has shown that in some early cases of deafness, due to degeneration of the auditory nerve, nicotinic acid has restored the function of hearing.

Page 110 - One great secret of body chemistry is vitamin cooperation and "balance." When the dietary intake is in perfect balance, with an adequate supply of all essentials, then good body metabolism occurs and we maintain full health.

Page 119 - I believe that the deficiency of Vitamin C is the most common cause of coronary thrombosis.

Page 126 - Clinicians in hospital practice have used Vitamin E with good results in cases of habitual abortion and threatened abortion.

In women, single massive doses of Vitamin E abolished the symptoms of uterine tenderness, cramps, hemorrhages and sacral backache and averted the impending toxaemia and interruption of pregnancy in some cases. In the human male, Vitamin E has been used successfully in a case of undescended testicle, in a case of impotence and gross atrophy of the testicles, and in a case for the production of normal spermatozoa.

Page 128 - And mineral deficiencies are deplorably common in the typical American diet, mineral deficiencies and the ills they bring are deplorably prevalent in American bodies.

Page 132 - It is the combination of vitamin-and-calcium deficiency that causes most of the world's low resistance to colds, susceptibility to dental caries, endocrine imbalance, and so on.

"The reprints and films referred to in paragraph 15, when taken as a group, expound the same false and misleading theme as does the booklet 'How to Get Well and Stay Well,' namely, that everyone suffers from dietary deficiencies due to (1) the influence of our devitalized and demineralized soil on the nutritive value of food, (2) food processing, (3) storage and transit delays, and (4) improper preparation and cooking. The said reprints, as does 'How to Get Well and Stay Well,' also emphasize the conclusion which is stated directly and succinctly on page 7 of the reprint 'Soil—A Foundation of Health' by Arnold P. Yerkes, (International Harvester Co.) Chicago, 1946: The fact is there is only one major disease, and that is malnutrition. All ailments and afflictions to which we may become heir are directly traceable to this major disease.

In addition to general statements of this character, the reprints specifically name certain 'ailments and afflictions' which are claimed to be the result of vitamin and mineral deficiencies. These are:

Cancer, heart disease, tuberculosis, mental disease, arthritis, rheumatism, influenza, osteomyelitis, paralysis, meningitis, pneumonia, myopia, hyperopia, nephritis, thyroid disease, abortion, gingivitis, hepatitis, orchitis, oophoritis, cystitis, diabetes, gastric ulcers, allergies, diarrhea.

in addition, dietary deficiencies in children are claimed to cause lowered resistance to:

Measles, scarlet fever, bronchopneumonia, middle ear disease, rheumatism, rheumatic disease, heart disease

and an increased tendency to:

Nasal catarrh, septic tonsils, adenoids, inflammed eyes, defective vision,

nervous instability and cardiovascular derangements.

"When the said reprints are used by distributors in the manner specified above, 'Nutrilite Food Supplement' is falsely and misleadingly represented and suggested as an effective treatment and cure and preventive for the conditions and diseases enumerated above. In addition, the weekly newsletter, 'Nutrilite News,' includes brief summaries of written articles describing the beneficial effects of vitamins and minerals. The information contained in these newsletters is used by distributors in the sale of the product to convey the false and misleading impression that all illnesses are due to vitamin and

mineral deficiencies and that 'Nutrilite Food Supplement' is an adequate treatment, preventive, and cure for such illnesses.

"19. Prior to 1945, the product 'Nutrilite Food Supplement' had little or no interstate market. In 1945 the defendants, Mytinger and Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, were given the exclusive right to promote and distribute this product. At that time a variation of the present labeling was introduced and the defendants' interstate business has steadily increased. At this time defendants have agents and distributors in almost every state of the union and profess to gross \$500,000 per month from the sale of 'Nutrilite.'

"20. The defendants have had sufficient warnings to put them on notice that the labeling of their product Nutrilite Food Supplement is violative of the Federal Food, Drug, and Cosmetic Act. On June 18, 1947, pursuant to Section 305 of the Act [21 U. S. C. 335], a Notice of Hearing was sent to Mytinger and Casselberry, then a partnership, informing them that the booklet 'How to Get Well and Stay Well' and other labeling matter was false and misleading. In response to this notice there apeared, on July 15, 1947, at the office of the Los Angeles District of the United States Food and Drug Administration, Lee S. Mytinger, William S. Casselberry and Lee J. Myers, attorney, representing Mytinger and Casselberry. There also appeared at this hearing, Carl F. Rehnborg and Lester L. Lev, representing Nutrilite Products Co. At this hearing, Mr. Myers, attorney for Mytinger and Casselberry, stated that he personally would revise all the labeling to bring it into compliance with the Act. Inconsequential changes in the labeling were made at this time. On September 16, 1947, a Notice of Hearing was sent to Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg, as individuals, and to Nutrilite Products Company. Written responses were received and Mr. Myers informed the Food and Drug Administration that the booklet, 'How to Get Well and Stay Well' had been entirely revised to comply with the Act. Printers proofs of the products' labels were submitted for approval but no proofs of the allegedly revised booklet or other labeling were received. The booklet as it finally appeared contained some changes in wording but as a whole it was still false and misleading. On September 20, 1948, a Grand Jury sitting in the jurisdiction of the United States District Court for the Southern District of California, Central Division, returned a true bill indicting Mytinger and Casselberry, a partnership, and Lee S. Mytinger, William S. Casselberry and Carl F. Rehnborg, as individuals, for violations of the Federal Food, Drug, and Cosmetic Act. This case is still pending. [This action was dismissed following the entry of the consent decree in this proceeding.] Because of its seriously misbranded condition, the United States Government, under section 304 (a) of the Act [21 U. S. C. 334 (a)], has instituted 11 seizure actions against the product, Nutrilite Food Supplement, in various United States district courts. These cases have not been tried. The only labeling changes effected by defendants as a result of the institution of these actions has been the deletion of the more obvious falsehoods and their replacement with more artful wording and the 'new language' designed to convey to the consumer the same information.

"21. The plaintiff believes that this product is seriously misbranded and constitutes a threat to the health of the consuming public. The booklet 'How to Get Well and Stay Well' as a whole, when used in the manner alleged herein, is calculated to convince the lay reader that the body can overcome every illness if 'Nutrilite Food Supplement' is added to the diet, despite the advice in several places that people should visit their medical doctors. The 'Sales Manual' specifically instructs the Nutrilite salesman to quote D. T. Quigley's book 'The National Malnutrition' at page 95 where it is stated:

To make up for past dietary sins, concentrated vitamins should be taken for six months to two years, in order that the individual may reach a point where, with his reserves restored, he can carry on a balanced diet.

The booklet, 'How to Get Well and Stay Well,' on page 20 contains these statements:

Actually, then, when a person has an ache or pain, a weakness, wasting, unsatisfactory feeling, a lesion, a symptom, or loss of physical capacity—in short, when he is ill, there are three courses of action open to him.

(1) He can reason that since his body needs all necessary building and regulating materials anyway, whether ill or well, he must make sure his body is getting all these essential items for proper rebuilding and regulating, and he will add these to his diet. Then he can wait long enough to give the body a chance to rebuild, and see if that is all he needs.

And on page 21:

This procedure should be acceptable to all concerned. First, if the ailment is chronic rather than acute, no harm can come from the use of the process of rebuilding through food and the nutrilites, since the ailment has likely been plaguing the person for considerable time and the sufferer is still alive. A few months devoted to rebuilding the body can hardly make things worse.

This advice if followed with respect to all illnesses may easily result in irreparable injury to health or even death. A delay of 6 months to 2 years in treating a chronic condition of cancer, heart disease or tuberculosis may well result in death. That 'Nutrilite Food Supplement' is sold for the treatment and cure of such serious ailments is evidenced also by the memorandum entitled 'action! Your chance to help,' which was sent to all Nutrilite distributors along with the weekly edition of 'Nutrilite News' on or about March 17, 1949. This memorandum solicits the aid of all Nutrilite distributors in securing users of Nutrilite to testify as to the efficacy of this drug in the treatment and care of: Cancer, tuberculosis, gallstones, prostate trouble, arthritis, heart trouble, liver trouble and kidney trouble and of any other 'reasonably serious ailment.'

"22. The plaintiff believes that the misbranding of this product has resulted and will continue to result in, injury and damage to the welfare of the consuming public, in that the defendants are attempting to and are in fact inducing consumers to purchase this product in reliance on representations made by and on behalf of the defendants that it will be effective in the treatment, cure and prevention of all diseases and conditions enumerated above, whereas this product will be ineffective when used for the treatment, prevention and

cure of such diseases and conditions.

"23. The defendants, Nutrilite Products, Inc., and Carl F. Rehnborg are in active concert and participation with the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, by manufacturing the drug 'Nutrilite Food Supplement' and by acting as scientific advisors in the distributional scheme and by making public appearances before distributor groups to explain that 'Nutrilite Food Supplement' contains a secret base of unusual therapeutic value and is the answer to man's search for health, which said explanations are false and misleading.

"24. Delay in enforcement action has resulted from an injunction granted

"24. Delay in enforcement action has resulted from an injunction granted by a three-judge court in the District of Columbia, 87 F. Supp. 650. The Supreme Court of the United States has recently reversed the lower court on the

ground that it acted without jurisdiction, 339 U.S. 594.

"25. As successive regulatory steps have been taken by the United States, the defendants have increased their word of mouth promotion and decreased the written, printed, and graphic matter in the distribution scheme. While defendants are contending that their written, printed, and graphic promotional material is innocuous, and merely offers Nutrilite Food Supplement as a dietary supplement, their distributors and agents are utilizing the information contained in this material and in fact are selling Nutrilite Food Supplement to the public as an effective treatment, preventive, and cure for all the common ailments. The plaintiff alleges that if defendants are forced by an injunction to discontinue their offensive labeling they will, unless enjoined, continue the merchandising of 'Nutrilite Food Supplement' through oral representations made by their distributors. In that case, the said drug would be misbranded within the meaning of 21 U. S. C. 352 (f) (1), in that its labeling would fail to bear adequate directions for use.

"26. The plaintiff is informed and believes that unless restrained by the court, the defendants will continue to introduce and deliver for introduction into interstate commerce the said article of drug misbranded within the meaning of 21 U. S. C. 352 (a) and 352 (f) (1). The plaintiff also is informed and believes that unless restrained by the court, the said defendants will con-

tinue to cause the said article of drug to be misbranded within the meaning of 21 U. S. C. 352 (a) and (f) (1) while held for sale after shipment in interstate commerce by directing the distributors to use oral and written testimonials obtained locally and by directing the said distributors to use written, printed, and graphic matter obtained locally to explain that 'Nutrilite Food Supplement' is useful in the treatment, prevention, and cure of all of the

ills that beset mankind.

PRAYER: "That the defendants, Mytinger & Casselberry, Inc., a corporation, and Nutrilite Products, Inc., a corporation, and Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg, individuals, and each and all of their officers, agents, representatives, servants, employees, and attorneys, and all persons in active concert or participation with any of them be perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction in interstate commerce the article of drug designated as 'Nutrilite Food Supplement,' or the same article by any other designation, or any similar article, (1) misbranded within the meaning of Section 502 (a) of the Act [21 U. S. C. 352 (a)] by virtue of the use of the aforesaid false and misleading written, printed, and graphic matter, or any other false or misleading written, printed, and graphic matter, in the manner aforesaid, or (2) misbranded within the meaning of Section 502 (f) (1) [21 U. S. C. 352 (f) (1)] in that the labeling of said article fails to bear adequate directions for the uses for which the said article is intended, in violation of Section 301 (a) of said Act [21 U. S. C. 331 (a)];

"That the aforesaid defendants and all persons in active concert or participation with them be perpetually enjoined from directly or indirectly doing or causing to be done any act, whether oral, written, or otherwise, in the manner aforesaid, or in any other manner, with respect to the aforesaid article, or similar article, while held for sale after shipment in interstate commerce which results in said article being misbranded, (1) within the meaning of Section 502 (a) [21 U. S. C. 352 (a)] in that the said written, printed or graphic matter is false and misleading or (2) within the meaning of Section 502 (f) (1) [21 U. S. C. 352 (f) (1)] in that the labeling of said article fails to bear adequate directions for the uses for which the said article is intended, in viola-

tion of Section 301 (k) of the Act [21 U.S. C. 331 (k)]; and

"That the defendants be required to tender to all purchasers of Nutrilite Food Supplement, past and present, a refund of all amounts collected by said defendants from said purchasers, as the sale price of said article; and that the plaintiff be given judgment for its costs herein and for such other and further relief as to the court may deem just and proper."

DISPOSITION: On November 16, 1950, the following motions were filed on behalf of the defendants: (1) a motion to drop Lee S. Mytinger and William S. Casselberry as defendants on the grounds that they were not necessary nor proper parties defendant; that a judgment against the corporation would bind them; that the defendants were not engaged in any of the acts complained of; and that the defense would impose upon said defendants great and unnecessary expense; (2) a motion to drop the Nutrilite Products, Inc., and Carl F. Rehnborg as defendants, on the ground that they were neither indispensable nor proper parties defendant; (3) a motion to dismiss the complaint on the ground that the complaint failed to state a claim for relief; (4) a motion to strike certain allegations from the complaint on the grounds that they were redundant, immaterial, impertinent, and scandalous; and (5) a motion for a more definite statement on the grounds that the complaint was vague and ambiguous. The motions were considered by the court on briefs filed by the parties, and on December 19, 1950, the court denied all of the said motions.

The defendants' answers to the complaint were filed on December 29, 1950. On or about this date, the defendants served requests for admission, which were in part answered and in part objected to by the Government. Subsequently, the court overruled certain of the Government's objections and

sustained the others; the Government then filed an amended answer to the request for admission. On January 10, 1951, the defendants filed a demand for a jury trial, which, however, was vacated on or about January 29, 1951, on motion of the Government.

On January 18, 1951, the Government filed a motion to strike portions of the defendants' answers to the complaint, on the grounds that they were immaterial and insufficient as a defense to this action. This motion was overruled in part and granted in part in an oral ruling from the bench.

On January 31, 1951, a motion was filed on behalf of the defendants, praying that the proceedings in the injunction suit be stayed pending the outcome of the case involving 10 actions against certain quantities of *Nutrilite Food Supplement*, which had been seized by process of libel in various Federal districts and which had been removed to the Northern District of California and consolidated for trial at San Francisco (reported in N. J. No. 3381). The defendants' motion for stay of proceedings was denied on February 2, 1951.

On February 14, 1951, the defendants moved, in the Northern District of California, for an order and injunction restraining the United States and its officers and the Honorable Ben Harrison, Judge for the Southern District of California, from proceeding with the trial of the injunction suit until disposition of the consolidated seizure actions, which motions were denied.

On February 9, 1951, the Government filed a motion to compel Carl F. Rehnborg to answer certain questions which he had refused to answer upon oral examination and to require the production of documents and records by Bernard Bailey, Lee S. Mytinger, and William S. Casselberry. The court ruled, on February 26, 1951, that Mr. Rehnborg need not answer the questions objected to by him on the grounds of self incrimination. The court further ruled that the records of the corporations may be subpensed and should be produced, and that the secret process for the identity of a solvent used in manufacturing could be inquired into by examination of other witnesses.

On February 14, 1951, the Government filed requests for admission. No answers were filed to these requests, and on April 6, 1951, the following consent degree of injunction was entered:

Harrison, District Judge: "Upon the consent of all parties, and before any testimony has been taken, and without any finding by the Court on any issue of fact or law, it is

Ι

"ORDERED, ADJUDGED, AND DECREED that this Court has jurisdiction of the subject matter hereof and of all the parties herein; and it is further

TT

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce the article designated as 'Nutrilite Food Supplement XX'; 'Nutrilite Food Supplement X'; 'Nutrilite Food Supplement X'; 'Nutrilite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by the following written, printed, or graphic matter or accompanied by any written printed, or graphic matter substantially to the same effect:

"'How To Get Well and Stay Well'—any edition; 'Sales Manual-Nutrilite Food Supplement'—any present and past editions; 'Agent's Manual'—any present or past editions; 'The National Malnutrition' by D. T. Quigley, M. D.; 'Man Alive, You're Half Dead!' by Daniel C. Munro, M. D.; 'You Can Live Longer Than You Think' by Daniel C. Munro, M. D.; 'Nutrilite News'—any past issue; 'Southern California News,'—any past issue; 'Modern Miracle Men' by Rex Beach, S. Doc. No. 264, 74th Cong. 2d Sess. (1941)—M. & C. Reprint No. 1; 'We Feed Our Hogs Better Than Our Children' by Fred Bailey, American Magazine (October, 1947), M. & C. Reprint No. 2; 'Nutrition and Pregnancy' by Bruce Bliven, reprinted from Ladies' Home Journal (November, 1947), M. & C. Reprint No. 3; 'The Miracles of Dr. Sples,' by Dickson Hartwell, reprinted from Colliers (January 31, 1948), M. & C. Reprint No. 4; 'Vitamins Are Not Drugs!' by Dr. Simon Benson, reprinted from The Apothecary (June, 1946) by Lee Foundation for Nutritional Research, M. & C. Reprint No. 5; 'The Latest on Vitamin Pills' by Clarence Woodbury, Woman's Home Companion (January, 1949), M. & C. Reprint No. 6; 'What Makes You Healthy?' by Winifred Raushenbush, Ladies Home Journal (March, 1949), M. & C. Reprint No. 7; 'Bang's Disease and Undulant Fever Are Due to Nutritional Deficiencies' by J. F. Wischhusen, American Feed and Grain Dealer, Minneapolis, Minnesota, (July, 1948), M. & C. Reprint No. 8; 'A Practical Way to Avoid Malnutrition' by Royal S. Lee, Lecture delivered at American Academy of Applied Nutrition, reprinted by Lee Foundation for Nutritional Research (April 17, 1948), M. & C. Reprint No. 9; 'Quotations on Vitamins,' M. & C. Reprint No. 10; 'Are We Starving to Death' by Neil M. Clark, reprinted from Saturday Evening Post (1945); 'Health Is On The Downgrade' by Henry Trautman, reprinted from Life Today (December, 1949); '"Food' For Thought' by Rev. Henry Retzek, reprinted from Priest Magazine (December, 1945); 'Living Should Be Fun' by Carlton Fredericks; 'Your Career as a Nutril

"Provided that any information derived from the foregoing publications used in devising new labeling shall not be prohibited if it conforms to all

of the provisions of the Federal Food, Drug, and Cosmetic Act.

Ш

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce the article designated as 'Nutrilite Food Supplement XX,' 'Nutrilite Food Supplement X,' 'Nutrilite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by any written, printed, or graphic matter which states, represents, or implies, directly or indirectly, that such article will or may be effective to prevent or adequately treat or cure any of the following named diseases and conditions: Arthritis, rheumatism, high blood pressure, abnormal blood count, Buerger's disease, cancer, leukemia, tumor, cerebral hemorrhage, stroke, apoplexy, diabetes, deafness, infection of ear, middle ear disease, astigmatism, cataract, near-sightedness, gall bladder trouble, hemorrhage connected with menopause, premature menopause, dysmenorrhea, prostate trouble, impotence in males, sterility, uterine cramps, uterine hemorrhages, angina pectoris, coronary occlusion, coronary thrombosis, heart disease, hypertensive heart disease, rheumatic heart disease, infantile paralysis, poliomyelitis, cystitis, kidney congestion, kidney stone, nephritis, pyrelitis, cirrhosis of the liver, hepatitis, sclerosis of the liver, multiple sclerosis, palsy, paralysis, Parkinson's disease, scarlet fever, measles, meningitis, pneumonia, smallpox, ulcers (duodenal, peptic, stomach, gastric), varicose veins, or any other symptom, disease or condition that is not within the allowable claims specified in paragraph V, including subparagraph 31. Nothing in this paragraph III shall prohibit the defendants, their officers, agents, distributors, representatives, servants, employees, attorneys and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise from selling or offering for sale Nutrilite Food Supplement solely as a food supplement to supplement or fortify the diet of any person who may have any of the diseases or conditions above mentioned.

IV

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivered or causing to be delivered for introduction in interstate commerce the article designated as 'Nutrilite Food Supplement XX,' 'Nutrilite Food Supplement X,' 'Nutrilite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by any written, printed, or graphic matter which states, represents, or implies, directly or indirectly that:

"1. There is only one major disease and that is malnutrition; and every ailment or affliction which the public is currently suffering or to which they may become heir is directly traceable to malnutrition.

"2. Most of the ills and diseases of human beings are the result of chemical

starvation of our bodies for vitamins and/or minerals.

"3. Physicians are trained in medicine, not nutrition, and are therefore not prepared to accept the proposition that many people's complaints may be, and probably are, caused by deficiencies of microfood factors; the 'medical approach' of doctors in ascribing illness and disease to poisons and germs is old fashioned.

"4. When a person has an ache or pain, a weakness, wasting, unsatisfactory feeling, a lesion, a symptom, or loss of physical capacity, in short, when he is ill, he can reason that since his body needs all necessary building and regulating materials anyway, whether ill or well, he will add a vitamin and mineral food supplement to his diet, then he can wait long enough to give the body a chance to rebuild and see if that is all he needs.

"5. Deficiencies of vitamins and/or minerals in the diet may show itself as one of the common or not so common deficiency diseases, including those most responsible for death in our 40's and 50's, whereas we should live in good health and vigor, and with full possession of our faculties, to the age of 90 or 100.

"6. Diagnosis of disease is not necessary because whatever the trouble or its medical name a vitamin and mineral food supplement will cause it to dis-

appear.
"7. The use of a vitamin and mineral food supplement will bring about a

condition of health.

"8. Every illness is the result of chemical imbalance and health is the result of chemical balance, and a vitamin and mineral food supplement will bring the body into chemical balance.

"9. The terms 'health nuisances,' 'chemical imbalance,' 'not-health,' 'poor nutrition,' 'malnutrition,' 'deficiency disease,' 'dietary deficiency,' 'deficiency ailment,' or 'dietary deficiency ailment' have the same meaning as every and all ailments, illnesses or sicknesses.

"10. The accessory food factors necessary to good health are called nutrilites in the text books of the bio-chemists; the term 'nutrilites' means vitamins,

chlorophyll, bios, inositol and many others.

"11. All vitamins and other accessory food factors originate in plant ma-

terial. "12. A food supplement which is capable of protecting against the ravages and pain of deficiency diseases must contain all the vitamins, including those which cannot be bought in the drug store, together with the nutrilites and

minerals so often lacking in our diet.

"13. A significant proportion of military service rejections during World Wars I and II were due to malnutrition or vitamin and/or mineral deficiencies in the diet.

"14. Distributors should use the process of elimination in selling a vitamin and mineral food supplement, through which it is reasoned that all diseases and incapacities except those due to germ invasions and accidents, are attributed to faulty nutrition.

"15. Any other representation not within the allowable claims specified in Paragraph V including subparagraph 31, which does not conform to the Fed-

eral Food, Drug and Cosmetic Act.

and it is further

"ordered, adjudged and decreed that the allowable claims that may be made as to the need for, or usefulness of, Nutrilite Food Supplement XX, Nutrilite Food Supplement X, and Nutrilite Food Supplement Junior, shall be limited to the following:

"1. These articles, when taken as directed, will supply to the user's diet the vitamins and minerals stated on the labels in the amounts and proportions

of the minimum daily requirements stated on their labels.

"2. The need in human nutrition has been established for the following vitamins and minerals contained in Nutrilite Food Supplement:

> Vitamin A Calcium Vitamin D Phosphorus Vitamin B-1 (Thiamin) Iodine Vitamin B-2 (Riboflavin) Copper Vitamin C (Ascorbic Acid) Iron Vitamin K

Vitamin B-6 Niacinamide

but the need in human nutrition has not been established for the following vitamins and minerals contained in Nutrilite Food Supplement:

> Vitamin E Manganese Inositol Zinc Folic Acid Cobalt Rutin Nickel Para-aminobenzoic Acid Fluorine Pantothenic Acid

Vitamin B-12 Biotin

"3. That a prolonged deficiency in the intake of any vitamin or mineral for which the need in human nutrition has been established (except Vitamin D, which may also be derived from exposure to sunlight) produces pathological conditions known as vitamin or mineral deficiency diseases, whereas the daily intake of a certain minimum quantity of such substances prevents the onset of such conditions.

"4. That a 'clinical deficiency disease' is one which is capable of being diagnosed by qualified physicians from generally recognized symptoms.

"5. That a 'sub-clinical deficiency condition' is one, the symptoms of which are not sufficiently definite or apparent, as to be capable of diagnosis.

"6. That 'sub-clinical deficiency conditions' do exist in the United States. "7. All of the B-Complex vitamins for which the need in human nutrition has been established, viz: vitamin B_1 (thiamine), vitamin B_2 (riboflavin), niacin, and vitamin B_6 (pyridoxine), are contained in Nutrilite.

'8. If any representations are made to sell the need for Nutrilite Food Supplement, they shall not relate to the vitamins and minerals for which the need in human nutrition has not been established, other than statements which conform to all provisions of the Food, Drug and Cosmetic Act and are based upon reliable scientific evidence of the value of these substances.

"9. If any representations are made to sell the need for food suplementation with Nutrilite Food Supplement, such representation shall be that supplementation may be needed only if the user's diet is deficient in one or more of the vitamin and mineral nutrients for which the need in human nutrition has

been established.

"10. If the non-specific symptoms specified in the following paragraphs are mentioned, it shall be explained that if any such symptom persists it may be a danger signal for serious disease having no relationship to a vitamin or mineral deficiency.

"11. If clinical vitamin and mineral deficiency diseases (xerophthalmia, rickets, osteoporosis, beriberi, ariboflavinosis, scurvy, or pellagra) are discussed, it shall be explained that such diseases are rare in the United States.

"12. If a claim is made that death may result to human beings from a vitamin and/or mineral deficiency, there shall be associated with it a statement that this occurs only after prolonged and severe deficiencies of the vitamins and minerals needed in human nutrition and that such deaths are rare in the United States.

"13. If a claim is made that a symptom may be due to a sub-clinical vitamin or mineral deficiency, there shall be associated with the claim a qualification that Nutrilite Food Supplement would be of benefit only if the symptom resulted from a deficiency of one or more of the vitamins or minerals contained

in Nutrilite Food Supplement.

"14. The vitamins and minerals for which the need in human nutrition has been established are needed in certain minimum daily amounts for the proper

growth and vigor of children.

"15. If a claim is made that a deficiency of vitamin A may cause nutritional night blindness, or lowered resistance to infection of the mucous membranes of the eye or other organs, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin A has been less than the minimum daily requirement over a prolonged period, and (2) that these are non-specific symptoms in that they may be caused by any of a great number of conditions or may have functional causes; and (3) that such non-specific symptoms do not of themselves prove a nutritional deficiency.

"16. If the claim is made that persons suffering from chronic diarrhea require greater amounts of Vitamin A, it shall be explained that this is due to the evacuation of the vitamin before it can be absorbed by the body.

"17. If any claim is made to the effect that a deficiency of vitamin B_1 (thiamine), vitamin B_2 (riboflavin), and/or niacin may be the cause of nervousness, loss of appetite, neuritis, loss of muscle tone, digestive upsets, diarrhea, vague aches and pains, fatigue, irritability, headache, dizziness, dryness of the hair or skin, mental depression, insomnia, indigestion, loss of weight, constipation, weakness, reddening of the lips, or sores about the angles of the mouth, swelling and redness of the tongue, or inflammation of the mouth, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin B_1 , vitamin B_2 , and niacin is less than the minimum daily requirement over a prolonged period; (2) that these are non-specific symptoms in that they may be caused by any of a great number of conditions or may have functional causes; and (3) that such non-specific symptoms do not of themselves prove a nutritional deficiency.

"18. Vitamin B₁ (thiamine) tends in some cases to relieve the neuritis of

alcoholism and the neuritis of pregnancy.

"19. If it is claimed that a deficiency of vitamin C leads to dental caries, anemia, defective teeth and gums, sponginess of the gums, soreness and bleeding of the gums, pyorrhea, some gum infections, loss of appetite, and local hemorrhages of the mucous membranes of the nose, mouth, gums and about the face, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin C is less than the minimum daily requirement over a prolonged period, (2) that these conditions, while they may be concomitant signs of a vitamin C deficiency, do not of themselves prove a vitamin C deficiency, and (3) that these symptoms are non-specific and may be caused by any of a great number of conditions or may have functional causes.

"20. It may be claimed that a deficiency of vitamin D (whether dietary or not) or a deficiency of calcium in the human diet may produce rickets in infants or osteoporosis in adults; that vitamin D aids in the utilization of calcium and phosphorus, and is effective when adequate amounts of these minerals are present in the diet. It may be claimed that vitamin D promotes the utilization of calcium and phosphorus in the human body; that a deficiency of vitamin D (less than 400 units per day) or calcium, (less than 750 milligrams per day) over a prolonged period may cause poor bone and tooth development

in the growing child; and that during pregnancy and lactation there is an increased need for calcium, phosphorus, and iron. It may be claimed that an adequate daily supply of vitamin D (whether obtained from the diet, from dietary supplementation, or from exposure of the body to sunlight) may be useful in preventing or arresting dental caries in children when calcium and phosphorus are liberally supplied and the diet is adequate with respect to other nutrients.

"21. It may be claimed that calcium is one of the essential factors in the proper coagulation of the blood; and that in some cases the administration of calcium to pregnant women will relieve muscular soreness, muscular spasms,

muscular numbness, tingling of the muscles.

"22. That where whole wheat bread forms an important part of the diet, the

need for calcium is increased.

"23. It may be claimed that a deficiency of iron in the diet may cause iron deficiency anemia and that an adequate supply of iron is one of the essential factors in blood building. If it is claimed that a deficiency of iron in the diet may cause lack of energy or palpitation of the heart, it shall be explained (1) that these symptoms could occur only when the daily intake of iron is less than the minimum daily requirement over a prolonged period; (2) that these symptoms do not of themselves prove an iron deficiency; and (3) that these symptoms are non-specific and may be caused by any of a great number of conditions or may have functional causes.

"24. It may be claimed that a deficiency of iodine in the human diet will

cause simple goiter.

"25. It may be claimed that a deficiency of vitamin K in the human body leads to a tendency to excessive bleeding from minor wounds.

"26. That the need for vitamin Be (pyridoxine) in human nutrition was

established during the year 1950.

"27. That a deficiency of copper does not produce any known clinical disease, but copper is necessary for the utilization of iron in the human system.

"28. Alfalfa, parsley, and watercress in the Nutrilite Base contribute small amounts of some of the vitamins and minerals for which the need in human

nutrition has been established.

"29. It may be claimed that diets may be lacking in the vitamins and minerals for which the need in human nutrition has been established, by reason of poor dietary habits, the improper selection of foods, unbalanced menus and the loss of a portion of the water-soluble vitamins through excessive cooking, storage, and processing.

"30. It may be claimed that many physicians who practice obstetrics supplement the diets of expectant mothers with vitamins and minerals known to

be needed in human nutrition.

"31. That the specifications of the foregoing allowable claims shall not preclude the making of other claims or representations which conform to all the provisions of the Federal Food, Drug and Cosmetic Act including representations based upon generally accepted scientific facts in the field of nutrition; nor shall the foregoing specifications preclude the making of statements or representations which are supported by reliable scientific opinion, although not supported by the consensus of scientific opinion, provided the statements or representations are qualified by an explanation that a difference of reliable scientific opinion respecting the same does exist; and in the event of conflict between the provisions of this subparagraph 31 and any other provision of this decree the provisions of this subparagraph 31 shall prevail.

VI

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction in interstate commerce the article designated as 'Nutrilite Food Supplement,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, unless its labeling

states and enumerates all the purposes and conditions for which the article is intended (by the person who introduced it or caused it to be introduced or who delivered it or caused it to be delivered for introduction into interstate commerce) when introduced into interstate commerce to be used.

VII

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from doing or causing to be done any of the following acts or any acts substantially to the same effect, whether oral, written or otherwise, with respect to the aforesaid article, or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, while held

for sale after shipment in interstate commerce:

"1. The use, in the sale of Nutrilite Food Supplement, of any of the written, printed, or graphic matter enumerated in paragraph II, or of any other written, printed, or graphic matter substantially to the same effect, including but not limited to the following, none of which was shipped in interstate commerce by defendants herein: 'Soil, A Foundation of Health' by Arnold P. Yerkes, International Harvester Co. (Chicago, 1946); 'Cancer, a Nutritional Deficiency' by J. R. Davidson, reprinted from *Question Mark* (February, 1943); '— for Heart Disease: Vitamin E' by J. D. Ratcliff, reprinted from *Coronet* (October, 1948); 'The Prevention of Recurrence in Peptic Ulcer' by D. T. Quigley, Lee Foundation for Nutritional Research; 'The Need for Vitamins' by L. Stambovsky, Lee Foundation for Nutritional Research; 'Talking about Food' by George Tyner, reprinted from Journal of the American Academy of Applied Nutrition (Autumn, 1947); 'Why We Need Vitamin E' by August Pacini; 'You Can't Build a Live Body with Dead Food' and 'Why Should You Use Nutrilite'; 'How to Get Well and Stay Well'—General Church Edition; or any written, printed, or graphic matter not expressly authorized in writing by defendant Mytinger & Casselberry, Inc.

"2. The use, in the sale of Nutrilite Food Supplement, of any written, printed, or graphic matter which states, represents or implies that Nutrilite Food Supplement, and the Nutrilite Food Supplement will be offertive see a properties of degrate treatment to

Food Supplement will be effective as a preventive, adequate treatment, or cure of any disease, condition, or symptom covered by paragraph III, or which includes any of the representations prohibited by paragraph IV or any representation substantially to the same effect as those prohibited by paragraph IV, or any other representation that is not in conformity with the allowable

claims of paragraph V including subparagraph 31.

"3. Representing that Nutrilite Food Supplement is useful in the prevention, treatment, or cure of any disease, condition, or symptom that is not stated and/or enumerated in the labeling thereof.

VIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that in applying or enforcing the provisions of the foregoing paragraphs of this decree any statement, representation, or implication contained in a testimonial, whether upon any written, printed, or graphic matter (including wire or tape recordings) or made orally, may be made if allowed under the claims authorized in paragraph V including subparagraph 31 and shall be regarded as if made directly by the person using the testimonial or causing it to be used.

IX

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendant Mytinger & Casselberry, Inc., shall direct all distributors to forward to it all written, printed, and graphic matter in their possession obtained from Mytinger & Casselberry, Inc., the use of which is prohibited by this decree, and it shall not again be

used as labeling; and the defendant Mytinger & Casselberry, Inc., shall direct all distributors to discontinue the use in the sale of Nutrilite Food Supplement of any written, printed or graphic matter not expressly authorized in writing by it.

 \mathbf{x}

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly employing the following practices in their sales program:

"1. Authorizing a beginning distributor to undertake sales prior to his completion of initial training and his approval by Mytinger & Casselberry, Inc.

"2. Authorizing persons to distribute Nutrilite, or to sponsor distributors of Nutrilite, before they have been instructed as to the allowable and prohibited claims of this decree.

"3. Making any representation as to the qualifications and professional background of any person associated with Nutrilite Products, Inc., or Mytinger & Casselberry, Inc., which is not expressly authorized in writing by Mytinger & Casselberry, Inc., and Nutrilite Products, Inc.

$\mathbf{x}\mathbf{I}$

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendant Mytinger & Casselberry, Inc., shall call this decree to the attention of every present distributor who sells or offers for sale Nutrilite Food Supplement and require each such distributor to sign a written statement that he has read this decree.

XII

and it is further

"ORDERED, ADJUDGED, AND DECREED that all written, printed, and graphic matter used in the future in the merchandising of Nutrilite Food Supplement may at defendants' option first be submitted to the United States Food and Drug Administration for inspection and comment which shall be made within a reasonable time, and in the event the defendants disagree with the opinion of the Food and Drug Administration or upon the failure of the Food and Drug Administration to inspect and comment within a reasonable time respecting such labeling, or without submitting such written, printed, or graphic matter to said Administration, they may seek modification of this decree to authorize its use before it is distributed to agents or distributors.

XIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that an indictment dated September 15, 1948, returned to this Court against Mytinger & Casselberry, a partnership, and Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg, as individuals, No. 20289, be and the same is hereby dismissed; and that the consolidated libel proceedings against Nutrilite Food Supplement in the United States District Court for the Northern District of California, Southern Division, bearing numbers 24792–6, 25800, 25801, 25804, 25809, and 25817, shall be terminated pursuant to stipulation between the parties.

XIV

and it is further

"ORDERED, ADJUDGED, AND DECREED that nothing in this decree shall be construed as to prevent defendants from doing anything which is authorized under or by the Federal Food, Drug and Cosmetic Act, as amended, or any other provision of law, nor shall this decree deprive said defendants of the immuni-

ties conferred by said Act as now in force or as hereafter amended, and in the event of conflict between this paragraph and any other provision of this decree, the provisions of this paragraph shall prevail.

and it is further

"ORDERED, ADJUDGED, AND DECREED that in applying or enforcing the provisions of this decree, any act done or any statement or representation made by any distributor of Nutrilite Food Supplement, which act, statement, or representation was neither done nor made, nor caused to be done or made, by the defendants Mytinger & Casselberry, Inc., or Nutrilite Products, Inc., their officers, employees, or persons acting under authority from them, shall be deemed and regarded as solely the act, statement, or representation of the distributor.

XVI

and it is further

"ORDERED, ADJUDGED, AND DECREED that all claims for relief presented by the pleadings herein which are not specifically granted by this decree are hereby waived.

XVII

and it is further

"ORDERED, ADJUDGED, AND DECREED that this action be, and it hereby is, dismissed as to the defendants Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg.

XVIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that jurisdiction of this Court is retained for the purpose of enabling any of the parties to this judgment to apply at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this judgment or for modification of any of the provisions thereof and for the purpose of enforcing compliance therewith and the punishment of violations thereof. Nothing herein shall prejudice the right of any party to move the Court for modification of this judgment in the event of changed conditions of law, fact, or scientific opinion.

STIPULATION

"It is stipulated between the parties that the libel proceedings against Nutrilite Food Supplement pending in the United States District Court for the Northern District of California, Southern Division, bearing numbers 24792-6, 25800, 25801, 25804, 25809 and 25817 present no questions for adjudication for the reasons that (1) the products may have become below label potency and therefore unmarketable by reason of lapse of time, and (2) the use of the labeling involved has been covered by a final consent decree entered in the District Court of the United States for the Southern District of California in

United State v. Mytinger & Casselberry, Inc. et al., No. 10344-BH. "Now, therefore, upon consent and before any testimony has been taken and without any findings by the Court on any issue of fact or law, a final order may be made by the United States District Court for the Northern District of California, Southern Division, in each of said libel proceedings, directing the United States Marshals for the districts in which the shipments of said Nutrilite Food Supplement are under seizure, to deliver them to appropriate charitable institutions, for use by the inmates of the institutions, with an explanation that they may be below label potency and directing that the labeling be delivered to Mytinger & Casselberry, Inc., for disposition in accordance with paragraph IX of the final consent decree entered in the Southern District of California. The cost bonds filed in said libel proceedings may be discharged and the moneys deposited as cost bonds may be returned to Claimant Mytinger & Casselberry, Inc.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3381 TO 3383

PRODUCT

			N. J. No.
Nutrilite	Food	Supplement	3381-3383

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

Casselberry, W. S.:	N. J. No.
Nutrilite Food Supplement	3383
Mytinger, L. S.:	
Nutrilite Food Supplement	3383
Mytinger & Casselberry, Inc.:	
Nutrilite Food Supplement	3381-3383
Nutrilite Products, Inc.:	
Nutrilite Food Supplement	3383
Rehnborg, C. F.:	
Nutrilite Food Supplement	3383

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3384-3400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

Charles W. Crawford, Commissioner of Food and Drugs. Washington, D. C., August 20, 1951.

CONTENTS*

	Page		Page
New drug shipped without effective application	380	Drugs and devices actionable be- cause of failure to bear adequate directions or warning state- ments—Continued	
for which none had been issued	380	Drugs for veterinary use Drugs and devices actionable be- cause of deviation from official	383
cause of failure to bear ade- quate directions or warning statements	281	or own standards	384
Drugs for human use		cause of false and misleading	385

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3386, 3387; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3386, 3387.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3384. TB-1 tablets. U. S. v. 338 Bottles, etc. (F. D. C. No. 31055. Sample No. 17965-L.)

LIBEL FILED: April 11, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about April 5, 1951, by Stanley Lindo and Co., for account of the Strand Pharmacal Corp., Los Angeles, Calif., consigned to Bangkok, Thailand.

PRODUCT: 338 bottles, each containing 100 tablets, and 54 bottles, each containing 1,000 tablets, of TB-1 at Long Beach, Calif.

Label, IN Part: "T-B RX Strand Brand of TB-1 Each tablet provides Para-Acetylamino Benzaldehyde Thiosemicarbazone 25 mg."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: May 2, 1951. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3385. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 69 Cartons * * * *. (F. D. C. No. 30288. Sample No. 85882-K.)

LIBEL FILED: On or about December 6, 1950, Northern District of Texas.

Alleged Shipment: On or about October 6, 1950, from Brookfield, Ill.

PRODUCT: 69 cartons, each containing 1 tube, of Dr. Merrick's Ear Canker Creme at Dallas, Tex.

Label, IN Part: (Carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin. Tyrothricin, 2 Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate * * * Net Contents ½ Ounce."

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess, namely (on display carton) "contains * * * aureomycin," (on retail carton) "Active Ingredients: Aureomycin," and (on leaflet enclosed in retail carton) "Aureomycin and Tyrothricin * * * By combining the two anti-biotics we obtain a very desirable synergistic action resulting in more effective curative action than when either Aureomycin or Tyrothricin is used separately," since the article contained an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the statements in the labeling of the article, which are quoted above in the adulteration charge, were false and misleading as applied to the article, which contained an inconsequential trace, if any, of aureomycin; and, Section 502 (1), the article purported to be and was represented as a drug composed in whole or in part of aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 4, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

- 3386. Misbranding of pentobarbital sodium capsules. U. S. v. Bunting & Son, Inc. Plea of guilty. Fine, \$800. (F. D. C. No. 29460. Sample Nos. 2936-K to 2939-K, incl.)
- Information Filed: October 17, 1950, Eastern District of Tennessee, against Bunting & Son, Inc., Bristol, Tenn.
- INTERSTATE SHIPMENT: From the States of Ohio and Illinois into the State of Tennessee, of quantities of pentobarbital sodium capsules.
- ALLEGED VIOLATION: On or about August 8, 11, 15, and 22, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged and sold without a prescription, which acts resulted in the capsules being misbranded.
- NATURE of CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents. Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use, in that the directions "One capsule at bedtime as needed for rest," borne on the labeling, were not adequate directions for use.

- Disposition: March 5, 1951. A plea of guilty having been entered, the court imposed a fine of \$800 against the defendant.
- 3387. Misbranding of phenobarbital tablets. U. S. v. Nicholas Paris (Paris Drug Store). Plea of nolo contendere. Defendant fined \$500 and placed on probation for 1 year. (F. D. C. No. 29993. Sample Nos. 49741-K, 49743-K, 75194-K.)
- Information Filed: December 20, 1950, District of Colorado, against Nicholas Paris, trading as the Paris Drug Store, Denver, Colo.
- Interstate Shipment: On or about February 28, 1950, from the State of Missouri into the State of Colorado, of a quantity of phenobarbital tablets.
- ALLEGED VIOLATION: On or about April 3, 6, and 10, 1950, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the tablets to be repackaged and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged *phenobarbital tablets* failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative

and in juxtaposition therewith the statement "Warning-May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions, namely, "One tablet three times a day fifteen minutes before meals and at bedtime" and other similar directions borne on the labeling were not adequate directions for use.

DISPOSITION: March 7, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$500 against the defendant and placed him on probation for 1 year.

3388. Misbranding of male hormone tablets. U. S. v. Marvin Nashkin (Gold Seal Pharmacal Co.). Plea of guilty. Fine of \$250, plus costs. (F. D. C. No. 29432. Sample No. 57056-K.)

Information Filed: June 28, 1950, Northern District of Ohio, against Marvin Nashkin, trading as the Gold Seal Pharmacal Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about November 28, 1949, from the State of Ohio into the State of New Jersey.

Label, In Part: "Male Hormone (Methyl Testosterone) Regular Directions For use by adult males mildly deficient in male hormones when small dosages of male hormones are prescribed or recommended by a physician for palliative relief of such symptoms. Daily recommended intake of one light tablet provides 5 mg. of Methyl Testosterone in specially prepared base for sublingual use. Suggested Dosage One light tablet upon arising before breakfast. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying leaflet entitled "Attention! Men! Hormones" were false and misleading. The statements represented and suggested that the article would be of value to adult males mildly deficient in male hormones; that it would be of value to men beginning to feel past their prime; that it would constitute an adequate and effective treatment for diminished energy and vitality, worry over general health, depressed feeling, fatigue, irritability, excessive nervousness, and other common symptoms of the male climacteric; and that it would be efficacious in bringing men happiness and a longer useful life. The article would not accomplish the purposes claimed, and it would not constitute an adequate and effective treatment for the conditions so represented and suggested.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions, in that the directions for use borne on the labeling of the article were not adequate directions for use.

Disposition: February 23, 1951. A plea of guilty having been entered, the court imposed a fine of \$250, plus costs, against the defendant.

3389. Misbranding of X-ray device. U. S. v. 1 Device * * *. (F. D. C. No. 30332. Sample No. 70276–K.)

LIBEL FILED: On or about December 28, 1950, Western District of Missouri.

ALLEGED SHIPMENT: Between April 10, 1942, and near the end of February 1947, from Toledo, Ohio.

PRODUCT: 1 X-ray device at Kansas City, Mo.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for the use of the device.

The libel alleged also that the device was being used solely for the removal of superfluous hair; that it was never intended to be used in the removal of superfluous hair; that such use is capable of causing cancer; and that the use of the device was dangerous to the operator and other occupants of the room in which the device was used.

DISPOSITION: March 23, 1951. Default decree of condemnation. The court ordered that the device be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

3390. Misbranding of Foxsep. U. S. v. 10 Cases * * * (F. D. C. No. 30862. Sample No. 25265-L.)

LIBEL FILED: On or about March 22, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about January 25, 1949, and March 24 and December 26, 1950, by the Fox Co., from Selbyville, Del.

PRODUCT: 10 cases, each containing 4 1-gallon bottles, of Foxsep at Bishop, Md. Examination disclosed that the product consisted of cod liver oil, hydrochloric acid, and iodine.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state the diseases or conditions of poultry for which the article was intended.

DISPOSITION: April 25, 1951. Default decree of condemnation and destruction.

3391. Misbranding of oil-acid-iodine. U. S. v. 19 Cases * * * (F. D. C. No. 30792. Sample No. 3162–L.)

LIBEL FILED: On or about March 3, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about January 8, 1951, by Midland-Western, Inc., from York, Pa.

PRODUCT: 19 cases, each containing 4 1-gallon bottles, of oil-acid-iodine at Snow Hill, Md.

Label, IN Part: "Oil-Acid-Iodine Prof. C. E. Lee Formula for Poultry Active Ingredients Cod Liver Oil (100D-1200A) Hydrochloric Acid Collodial [sic] Iodine Water."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the purpose for which the article was intended.

Disposition: April 3, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3392. Adulteration and misbranding of amphetamine hydrochloride tablets. U. S. v. Robert Brinton Morris (Uno Laboratories). Plea of not guilty subsequently retracted. Fine of \$100 on count 1; imposition of sentence on count 2 suspended and defendant placed on probation for 2 years. (F. D. C. No. 29452. Sample No. 46720-K.)

Information Filed: August 8, 1950, District of New Jersey, against Robert Brinton Morris, trading as Uno Laboratories, at Pitman, N. J.

ALLEGED SHIPMENT: On or about May 7, 1949, from the State of New Jersey into the State of West Virginia.

Label, in Part: (One bottle) "N-Methyl Amphetamine HCL (dl-Desoxyephedrine HCL) 10 Mgm. per Tablet"; (remainder of bottles) "Amphetamine HCL Tablets 10 Mgm. per Tablet."

Nature of Charge: Adulteration, Section 501 (d) (2), the tablets each containing 9.64 milligrams of racemic desoxyephedrine hydrochloride and containing no amphetamine hydrochloride had been substituted in whole or in part for tablets each containing 10 milligrams of amphetamine hydrochloride, which the article purported and was represented to be.

Misbranding, Section 502 (a), the label statements "N-Methyl Amphetamine HCL (dl-Desoxyephedrine HCL 10 Mgm. per Tablet" and "Amphetamine HCL Tablets 10 Mgm. per Tablet" were false and misleading since the tablets of the article contained no amphetamine hydrochloride.

DISPOSITION: April 20, 1951. A plea of not guilty having been retracted, the court imposed a fine of \$100 on count 1, suspended the imposition of sentence on count 2, and placed the defendant on probation for 2 years.

3393. Adulteration and misbranding of Conjugestoral tablets. U. S. v. 1 Bottle * * *. (F. D. C. No. 30765. Sample No. 4991–L.)

LIBEL FILED: March 7, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 14, 1950, by Corby-Franklin Associates, from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle of Conjugestoral tablets at Brighton, Mass.

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the product, which contained less than the stated amount of estrogens.

DISPOSITION: April 23, 1951. Default decree of condemnation and destruction.

3394. Adulteration and misbranding of prophylactics. U. S. v. 42 Cartons

* * *. (F. D. C. No. 30759. Sample Nos. 1494-L to 1496-L, incl.)

Libel Filed: On or about March 13, 1951, Northern District of Georgia.

^{*}See also No. 3385.

ALLEGED SHIPMENT: On or about September 15, 1950, and January 2, 1951, by the Zenith Drug Sales, Inc., from Philadelphia, Pa.

PRODUCT: 42 cartons of *prophylactics* at Atlanta, Ga. Examination of samples disclosed that 3.95 percent were either dried out and could not be unrolled or contained holes, and therefore were unsuitable for use.

Label, in Part: (Carton) "Zenith Lubri-Pak 1/2 Gross."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to an article that was either dried out and could not be unrolled or contained holes.

DISPOSITION: April 6, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3395. Misbranding of Bone Food (bone phosphate). U. S. v. 1 Drum, etc. (F. D. C. No. 30231. Sample No. S1871-K.)

LIBEL FILED: November 9, 1950, Southern District of Florida.

Alleged Shipment: On or about August 15, 1950, from Chicago, Ill.

PRODUCT: 1 full drum containing 325 pounds and 1 partly filled drum containing 100 pounds of bone phosphate, and 102 1-pound bottles and 98 6½-ounce bottles of the same product relabeled Bone Food, at Miami, Fla., in possession of Carothers' Laboratory, together with a number of loose bottle labels, a number of circulars entitled "Carothers' Laboratory To The Physician," and a number of placards entitled "Your Bones Can Be Like This."

Examination showed that the *Bone Food* contained the declared proportion of calcium and phosphorus but less than 1 percent of magnesium.

RESULTS OF INVESTIGATION: The article contained in the bottles was repackaged from one of the above-mentioned drums at the point of destination. The consignee had the labels, circulars, and placards printed, and these circulars and placards were sent to customers with initial shipments of the repackaged product.

Label, In Part: (Drum) "Bone Phosphate"; (bottle) "Carothers' Bone Food #1 Mineral Supplement To Your Diet Analysis: Calcium 33% Phosphorus 15% Magnesium 14% Iron 710 ppm Zinc 30 ppm Copper 5 ppm Manganese 4 ppm Fluorine 400-500 ppm."

Nature of Charge: Misbranding, Section 502 (a), the labeling of the articles in the drums and bottles, namely, the bottle labels, circulars, and placards, contained statements which were false and misleading. The statements represented and suggested that the articles were an adequate and effective treatment for arthritis, bone ailments, rheumatism, tooth and gum disorders, high blood pressure, and low blood pressure; that they were effective to insure the growth of normal, healthy, and strong bones and joints, and healthy nails and teeth; and that they were effective to prevent dental caries, abscesses of the teeth, gum disorders, and death from rheumatic heart disease. The articles were not an adequate and effective treatment for such diseases and conditions, and they were not effective for the purposes stated and implied. The articles were misbranded while held for sale after shipment in interstate commerce.

^{*}See also Nos. 3385, 3388, 3392-3394.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 12, 1951. Default decree of forfeiture and destruction.

3396. Misbranding of Dr. Burnett's New Cold Remedy. U. S. v. 18 Bottles * * * (F. D. C. No. 30843. Sample No. 2759-L.)

LIBEL FILED: February 16, 1951, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about January 4, 1951, by Dr. Burnett Medicine Co., Inc., from Hillsville, Va.

PRODUCT: 18 6-ounce bottles of Dr. Burnett's New Cold Remedy at Mount Airy, N. C. Examination disclosed that the product consisted essentially of water, with small proportions of materials extracted from plant products.

Label, in Part: (Bottle) "Dr. Burnett's New Cold Remedy Made From Botanical Drugs Contains the Following Sassafras, Pinus (Alba), Ulmus Fulva, 'Populus.'"

Nature of Charge: Misbranding, Section 502 (a), the label statement "Cold Remedy * * * recommended for the relief of colds" was false and misleading since the article was not effective for the purpose recommended.

DISPOSITION: April 13, 1951. Default decree of condemnation and destruction.

3397. Misbranding of Dr. Burnett's Preparation. U. S. v. 41 Bottles, etc. (F. D. C. No. 30842. Sample No. 2865-L.)

LIBEL FILED: February 19, 1951, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about January 18, 1951, by Dr. Burnett Medicine Co., Inc., from Hillsville, Va.

PRODUCT: 41 1-quart bottles and 15 1-pint bottles of Dr. Burnett's Preparation at Welch, W. Va., together with a number of large display cards and a number of circulars relating to the product. Examination disclosed that the product consisted essentially of water, with small proportions of materials extracted from plant products.

Label, in Part: (Bottles) "Dr. Burnett's Preparation * * * Made From Botanical Drugs * * * Contains the Following: 'Populus,' Cornus Florida,' Pinus (Alba), Pinus (Virginia), Sassafras, Aralia Nudicaulis, Salix, Prunus (some species), Various species of Rubus, Carya (Hicoria), Prunus, Magnolia Acuminate, Nyssa Sylvatica, Ulmus Fulva."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements appearing in the labeling of the article were false and misleading since the article was not effective for the purposes recommended: (Label) "recommended for tonic. Many have used it for other ailments and report satisfactory results"; (large display card) "For Good And Better Health"; and (circular) "'I suffered over ten years with cough, also had rheumatism in my arms and legs so bad that I couldn't work,' 'I tried different kinds of medicines and remedies, but they all failed to bring me relief,' 'A friend of mine persuaded me to try Dr. Burnett's "New Medicine." After taking it one month I improved and after five months I fully recovered and I feel like a new man now,' 'I gained back my lost weight and strength. I have been well for three years now. I can eat and sleep fine and work hard every day,' and 'I think Dr. Burnett's "New Medicine" is wonderful. It brought me relief after everything else I tried had failed."

DISPOSITION: April 5, 1951. Default decree of condemnation and destruction.

3398. Misbranding of mineral oil. U. S. v. 80 Cases * * *. (F. D. C. No. 30770. Sample No. 1805-L.)

LIBEL FILED: March 13, 1951, Southern District of Georgia.

ALLEGED SHIPMENT: On or about October 9, 1950, by the Cumberland Mfg. Co., from Nashville, Tenn.

PRODUCT: 80 cases, each containing 12 1-pint bottles, of mineral oil at Augusta Ga.

LABEL, IN PART: (Bottle) "Dr. Lane's Mineral Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement borne on the bottle label, namely, "As Mineral Oil does not disturb the system it is a safe intestinal lubricant for * * * nursing or expectant mothers," was false and misleading since the article was not safe for use by nursing or expectant mothers.

DISPOSITION: April 16, 1951. Default decree of condemnation and destruction.

3399. Misbranding of Lazarin ointment. U. S. v. 1 Drum, etc. (F. D. C. No. 29716. Sample No. 73215-K.)

LIBEL FILED: September 6, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 18, 1950, from Newark, N. J., by the Old Empire Mfg. Chemists.

PRODUCT: Lazarin ointment. 1 100-pound drum; 120 dozen cartons, each containing a 1¼-ounce tube; and 60 dozen cartons, each containing a 4-ounce tube, in possession of the Lazarin Co., Oceanside, N. Y.

RESULTS OF INVESTIGATION: The product was shipped in interstate commerce in 3 drums, and portions had been repackaged in tubes by the consignee. The tubes were enclosed in cartons, and a leaflet entitled "Lazarin Ointment" was inserted in each carton. At the time of the investigation, approximately 100 pounds of the ointment remained in one of the drums. The drums at the time bore no labeling but the word "Ointment." This fact was reported to the United States Attorney, and the libel prepared by him charged that the product in the drums was misbranded for failure to bear labeling required by Sections 502 (b) (1) and (2) and 502 (e) (2).

Subsequent to the filing of the libel, the shipper stated that the drums when shipped bore tags or marks containing the name and address of the distributor and a statement of the net weight; but he admitted that the drums failed to bear a statement of the active ingredients, as required by Section 502 (e) (2), and that no written agreement as to labeling was in effect pursuant to regulations promulgated under Section 503. However, no defense was interposed, and no action was taken to have the libel amended.

Label, In Part: (Carton) "An Antibiotic Ointment Lazarin * * * Tyrothricin (.175 mg. per gram)"; (tube) "Lazarin With Tyrothricin An Antibiotic ointment containing Tyrothricin (.175 mg. per gm.)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the repackaged product were false and misleading: (Carton) "Tyrothricin (.175 mg. per gram) * * * Combats Infection," (tube) "Tyrothricin (.175 mg. per gm)," and (leaflet) "Lazarin contains Tyrothricin, a * * * antiseptic, for the prevention of infection * * * Prompt use of Lazarin with Tyrothricin, safeguards your babies health * * * the anti-infective properties of Tyrothricin * * * Lazarin has proven itself extremely effective in the treatment of the following conditions: Varicose

Ulcers Surface Infections Diabetic Ulcers Impetiginous Conditions." The article contained less than .175 mg. of tyrothricin per gram; it was not an antiseptic; it would not prevent infection; and it would not be an effective treatment for the stated conditions. The repackaged portion was misbranded while held for sale after shipment in interstate commerce.

The libel alleged that the product in the drum was misbranded when introduced into and while in interstate commerce as follows: Sections 502 (b) (1) and (2), it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (e) (2), its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: January 30, 1951. Default decree of condemnation and destruction.

3400. Misbranding of Slenderform device. U. S. v. 4 Cartons * * *. (F. D. C. No. 27839. Sample No. 57045–K.)

LIBEL FILED: September 14, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about August 22, 1949, by the Miles Mfg. Co., from Charlotte, N. C.

PRODUCT: 4 cartons containing 25 Slenderform devices and a number of circulars entitled "Instructions For The Use Of The Slenderform Reducer And Home Massager," at Ridgewood, N. J. Examination disclosed that the device consisted of an electric motor so mounted as to vibrate during operation, attached to a handle and a belt.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the accompanying circulars were false and misleading since the device was not effective for the purposes stated and implied: "Slenderform Reducer * * ladies-and * * * gentlemen-massage away their fat and exhaustion in the privacy of the home. No bother, no effort-just relax and let Slenderform do it for you. When using Slenderform for reducing purposes * * * if you want to reduce the waist first, use it on the waist exclusively until desired results are obtained, then start on another portion of the body where it is most needed, and keep up this procedure until you have reduced all portions to your satisfaction * * * when reducing the waist * * * the reducer * * * should be placed * * * against the waist line * * * The Slenderform massager also is an excellent aid in general health. It stimulates circulation, helps restore and maintain your vitality, improves sleep * * * It aids elimination by the natural process of liver stimulation."

DISPOSITION: March 26, 1951. Default decree of condemnation. The court ordered that two of the devices be delivered to the Food and Drug Administration and that the remainder of the devices be destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3384 TO 3400 PRODUCTS

N. J	N.	J. No.	
Amphetamine hydrochloride tab-		Burnett's, Dr., New Cold Rem-	
lets {	3392	edy	3396
Bone Food (bone phosphate)			
		Colds, remedy for	3396

Midland-Western, Inc.:

0001 01001	01	0020112112	000
N	J. No. 1	NT.	J. No.
Conjugestoral tablets	3393	New Cold Remedy, Dr. Burnett's_	3396
Devices 3389, 3394,		Oil-acid-iodine	3391
Ear Canker Creme, Dr. Mer-	3400	Ointment	3399
rick's	3 385•	Pentobarbital sodium capsules	3386
Estrogenic substance	3393	Phenobarbital tablets	3387
	3390		3394
Foxsep	3399	Prophylactics	
Lazarin ointment		Reducing, device for	3400
Male hormone tablets	3388	Slenderform device	3400
Merrick's, Dr., Ear Canker	000=	TB-1 tablets	3384
Creme		Veterinary preparations 3390	
Methyltestosterone tablets		X-ray device	3389
Mineral oil	3398		
CHANDED WASHE	A COULTD	ERS, AND DISTRIBUTORS	
	ACTUR	ERS, AND DISTRIBUTORS	
N.	J. No.	N.	J. No.
Bunting & Son, Inc.:		Miles Mfg. Co.:	
pentobarbital sodium capsules_	3386	Slenderform device	3400
Burnett, Dr., Medicine Co., Inc.:		Morris, R. B.:	
Dr. Burnett's New Cold Rem-		amphetamine hydrochloride	
edy	3396	tablets	3392
Dr. Burnett's Preparation	3397	Nashkin, Marvin:	
Carothers' Laboratory:		male hormone (methyltesto-	
Bone Food (bone phosphate)	3395	sterone) tablets	3388
Corby-Franklin Associates:		Old Empire Mfg. Chemists:	
Conjugestoral tablets	3393	Lazarin ointment	3399
Cumberland Mfg. Co.:		Paris, Nicholas:	
mineral oil	3398	phenobarbital tablets	3387
Fox Co.:		Paris Drug Store. See Paris,	
Foxsep	3390	Nicholas.	
Gold Seal Pharmacal Co. See		Strand Pharmacal Corp.:	
Nashkin, Marvin.		TB-1 tablets	3384
Lazarin Co.:		Uno Laboratories. See Morris,	
Lazarin ointment	3399	R. B.	
Lindo, Stanley, & Co.:		Zenith Drug Sales, Inc.:	
TB-1 tablets	3384	prophylactics	3394

oil-acid-iodine _____ 3391

AN AREA STREET, STREET



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month \$15 per year

U. S. DEPAR I MENT UP AGRICULTURE

198' 6 T dES

Openie Williams

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3401-3420

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs.

WASHINGTON, D. C., August 24, 1951.

CONTENTS*

Pag	e J	Page
New drug shipped without effective application 39 Drugs actionable because of failure	Drugs for human use	400
to bear adequate directions or warning statements39 Drugs and devices actionable be-	Drug for veterinary use2 Index	
cause of deviation from official	9	

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3402, 3403, 3406, 3407, 3410, 3412; omission of, or unsatisfactory, ingredients statements, Nos. 3404, 3408, 3410-3412; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3402-3410, 3412, 3419, 3420; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3404, 3405, 3407, 3410-3412; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3420.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3401. ACTH. U. S. v. 1 Jar, etc. (F. D. C. No. 29802. Sample No. 73760-K.)

LIBEL FILED: October 19, 1950, Southern District of New York.

Alleged Shipment: On or about September 14, 1950, by the Princeton Laboratory Products Co., from Princeton, N. J.

PRODUCT: 1 jar containing 25.3 grams and 1 jar containing 21.6 grams of *ACTH*, together with 2 1-gram vials, 1 500-microgram vial, and 12 100-microgram vials of the same product at New York, N. Y.

LABEL, IN PART: "Biological Derivatives, Inc. * * * ACTH (Princeton)."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: January 24, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration, to be used for experimental purposes.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3402. Misbranding of Tuinal capsules and phenobarbital tablets. U. S. v. Bradley's Drug Store, Inc. Plea of guilty. Fine, \$800 (F. D. C. No. 29461. Sample Nos. 2354–K to 2358–K, incl., 3005–K to 3008–K, incl.)

Information Filed: October 30, 1950, Western District of Virginia, against Bradley's Drug Store, Inc., Bristol, Va.

INTERSTATE SHIPMENT: From the States of Indiana and Maryland into the State of Virginia, of quantities of Tuinal capsules and phenobarbital tablets.

ALLEGED VIOLATION: On or about August 9, 10, 12, 13, 15, 16, 19, 20, and 22, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated as, habit forming; and the repackaged drugs failed to bear labels containing the names, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions, namely, "One capsule at bedtime as needed for rest" and "Tabs one at bedtime if needed for rest," borne on the labeling of the repackaged drugs, were not adequate directions for use.

DISPOSITION: April 11, 1951. A plea of guilty having been entered, the court imposed a fine of \$800 against the defendant.

3403. Misbranding of phenobarbital tablets and Dexedrine Sulfate tablets.

U. S. v. Smith's of Spartanburg, Inc., and Richard B. Burnett. Pleas of nolo contendere. Fine of \$100 against corporation and \$25 against

individual; each defendant placed on probation for 5 years. (F. D. C. No. 30046. Sample Nos. 81885-K, 81886-K, 81981-K, 81982-K, 81988-K, 81989-K.)

INFORMATION FILED: February 21, 1951, Western District of South Carolina, against Smith's of Spartanburg, Inc., Spartanburg, S. C., and Richard B. Burnett, pharmacist for the corporation.

INTERSTATE SHIPMENT: From the States of Georgia and Pennsylvania into the State of South Carolina, of quantities of phenobarbital tablets and Dexedrine Sulfate tablets.

ALLEGED VIOLATION: On or about July 13 and 20 and August 9, 1950, while the drugs were being held for sale at Smith's of Spartanburg, Inc., after shipment in interstate commerce, various quantities of the tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

Smith's of Spartanburg, Inc., was charged with causing the acts of repacking and sale of the drugs involved in each of the 6 counts of the information; and, in addition, Richard B. Burnett, in two of the counts of the information, was charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Disposition: April 5, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against the corporation and \$25 against the individual and placed each defendant on probation for 5 years.

3404. Misbranding of Dexedrine Sulfate tablets and sulfathiazole tablets. U. S. v. East Side Pharmacy. Plea of guilty. Fine, \$250. (F. D. C. No. 30039. Sample Nos. 64613-K, 64624-K, 64625-K, 64650-K, 64658-K.)

Information Filed: March 29, 1951, District of South Dakota, against the East Side Pharmacy, a partnership, Sioux Falls, S. Dak.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of South Dakota, of quantities of Dexedrine Sulfate tablets and sulfathiazole tablets.

ALLEGED VIOLATION: On or about November 16, 1949, and January 10 and April 4 and 12, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (e) (1), the repackaged drugs failed to bear labels

containing their common or usual names, namely, Dexedrine Sulfate and sulfathiazole.

Further misbranding, Section 502 (f) (1), the repackaged *Dexedrine Sulfate tablets* bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the repackaged *sulfathiazole tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 12, 1951. A plea of guilty having been entered, the court imposed a fine of \$250.

3405. Misbranding of Dexedrine Sulfate tablets. U. S. v. Kenneth L. Pinard (Pinard Drug Co.). Plea of guilty. Fine, \$250. (F. D. C. No. 30037. Sample Nos. 64259-K, 64612-K, 64626-K, 64649-K.)

Information Filed: March 29, 1951, District of South Dakota, against Kenneth L. Pinard, trading as the Pinard Drug Co., Sioux Falls, S. Dak.

Interstate Shipment: From the State of Pennsylvania into the State of South Dakota, of quantities of Dexedrine Sulfate tablets.

ALLEGED VIOLATION: On or about September 22 and November 16, 1949, and January 10 and April 4, 1950, while the drug was being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drug to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets (in two sales) failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and (in each sale) statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets (in each sale) bore no directions for use.

DISPOSITION: April 12, 1951. A plea of guilty having been entered, the court imposed a fine of \$250 against the defendant.

3406. Misbranding of pentobarbital sodium capsules and Seconal Sodium capsules. U. S. v. Bristol Drug Corp. Plea of guilty. Fine, \$800. (F. D. C. No. 29456. Sample Nos. 2348–K to 2352–K, incl., 3010–K to 3013–K, incl.)

Information Filed: October 30, 1950, Western District of Virginia, against the Bristol Drug Corp., Bristol, Va.

INTERSTATE SHIPMENT: From the States of Georgia, Illinois, and Indiana, into the State of Virginia, of quantities of pentobarbital sodium capsules and Seconal Sodium capsules.

ALLEGED VIOLATION: On or about August 8, 11, 15, 16, 18, 19, 20, and 22, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated as, habit forming; and the label of the repackaged drugs

failed to bear the names, and the quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One at bedtime as needed for rest" and "One capsule at bedtime as needed for rest," borne on the labeling of the repackaged drugs, were not adequate directions for use.

- DISPOSITION: April 11, 1951. A plea of guilty having been entered, the court imposed a fine of \$800 against the defendant.
- 3407. Misbranding of Seconal Sodium capsules and amphetamine hydrochloride tablets. U. S. v. John R. Storms (Belmont Pharmacy). Plea of guilty. Fine of \$500 and sentence of 4 years in jail; prison sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 29439. Sample Nos. 23472-K, 23692-K, 23693-K, 53245-K.)
- INFORMATION FILED: September 28, 1950, Southern District of Texas, against John R. Storms, trading as the Belmont Pharmacy, Houston, Tex.
- INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Texas, of quantities of Seconal Sodium capsules and amphetamine hydrochloride tablets.
- ALLEGED VIOLATION: On or about January 15 and July 30, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged Seconal Sodium capsules and a portion of the amphetamine hydrochloride tablets failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear directions for use.

Further misbranding, Section 502 (d), the repackaged Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged amphetamine hydrochloride tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged amphetamine hydrochloride tablets failed to bear any warning against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- Disposition: March 14, 1951. A plea of guilty having been entered, the court imposed a fine of \$500 and a prison sentence of 4 years against the defendant. The prison sentence was suspended, and the defendant was placed on probation for 5 years.
- 3408. Misbranding of Benzedrine Sulfate tablets, Combisul-TD tablets, diethylstilbestrol tablets, and Desoxyn Hydrochloride tablets. U. S. v. H. W.

Miller Drug Co., Dilley A. Bowron, and J. Carl Berger. Pleas of guilty. Fine of \$200 against company and \$150 against each individual. (F. D. C. No. 30045. Sample Nos. 72139-K, 72495-K, 84157-K, 84428-K.)

INFORMATION FILED: Between February 19 and April 5, 1951, Southern District of Ohio, against the H. W. Miller Drug Co., a corporation, Columbus, Ohio, and Dilley A. Bowron and J. Carl Berger, pharmacists for the company.

INTERSTATE SHIPMENT: From the States of Indiana, Illinois, New Jersey, and Pennsylvania, into the State of Ohio, of quantities of Benzedrine Sulfate tablets, Combisul-TD tablets, diethylstilbestrol tablets, and Desoxyn Hydrochloride tablets.

ALLEGED VIOLATION: On or about June 19, 20, and 26, 1950, while the drugs were being held for sale at the H. W. Miller Drug Co., after shipment in interstate commerce, various quantities of the drugs were repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

The H. W. Miller Drug Co. was charged with causing the acts of repackaging and sale of the drugs involved in each of the four counts of the information; and, in addition, Dilley A. Bowron, in two of the counts, and J. Carl Berger, in the other two counts of the information, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (e) (2), the repackaged *Combisul-TD* tablets failed to bear a label containing the common or usual name of the active ingredients, namely, sulfathiazole and sulfadiazine; and, Section 502 (f) (2), the repackaged *Desoxyn Hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 5, 1951. Pleas of guilty having been entered, the court imposed a fine of \$200 against the company and \$150 against each individual.

3409. Misbranding of thyroid tablets, dextro-amphetamine phosphate tablets, triple sulfa tablets, and diethylstilbestrol tablets. U. S. v. Hial E. McGaughey (Drug Center). Plea of guilty. Fine, \$250. (F. D. C. No. 30005. Sample Nos. 61884-K, 76335-K, 76342-K, 76345-K.)

Information Filed: December 13, 1950, Eastern District of Illinois, against Hial E. McGaughey, trading as the Drug Center, East St. Louis, Ill.

INTERSTATE SHIPMENT: From the States of Missouri and New Jersey into the State of Illinois.

ALLEGED VIOLATION: On or about February 20 and 24 and March 26, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear ade-

quate directions for use in that the directions "Caution: To be taken only on advice of your doctor," "Caution: To be taken only as directed by your physician," "Caution: To be taken only as directed by doctor," and "Caution: To be used only as directed by your doctor," borne on the labeling of the repackaged drugs, were not adequate directions for use.

Further misbranding, Section 502 (f) (2), the repackaged dextro-amphetamine phosphate tablets and the triple sulfa tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Disposition: April 12, 1951. A plea of guilty having been entered, the court imposed a fine of \$250.

3410. Misbranding of thyroid tablets, diethylstilbestrol tablets, Amytal tablets, sulfadiazine and sodium bicarbonate tablets, and sulfathiazole tablets. U. S. v. Seybold Drug Co. Plea of guilty. Fine, \$700. (F. D. C. No. 29455. Sample Nos. 27088-K, 27092-K, 76522-K, 76523-K, 76525-K, 76527-K, 76544-K.)

INFORMATION FILED: September 26, 1950, Eastern District of Missouri, against the Seybold Drug Co., a corporation, Poplar Bluff, Mo.

INTERSTATE SHIPMENT: From the States of Michigan, Indiana, and Tennessee into the State of Missouri, of quantities of thyroid tablets, diethylstilbestrol tablets, Amytal tablets, sulfadiazine and sodium bicarbonate tablets, and sulfathiazole tablets.

ALLEGED VIOLATION: On or about December 28 and 29, 1949, and January 9, 10, and 12, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions "As directed" borne on the labeling of the diethylstilbestrol tablets and the sulfathiazole tablets and the directions "One as needed" borne on the labeling of a portion of the repackaged Amytal tablets were not adequate directions for use, and since the labeling of the remainder of the repackaged drugs bore no directions for use; and, Section 502 (b) (1), the repackaged drugs other than the sulfathiazole tablets bore no labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *Amytal tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *Amytal tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged diethylstilbestrol tablets and the sulfathiazole tablets bore no labels containing the common or usual name of the drugs; Section 502 (e) (2), the repackaged sulfadiazine and sodium bicarbonate tablets failed to bear the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (2), the labeling

of the sulfadiazine and sodium bicarbonate tablets and the sulfathiazole tablets bore no warning against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: March 27, 1951. A plea of guilty having been entered, the court imposed a fine of \$700 against the defendant.

- 3411. Misbranding of sulfadiazine and sodium bicarbonate tablets and thyroid tablets. U. S. v. John Frederick Borth, Jr. Plea of guilty. Fine, \$200. (F. D. C. No. 29443. Sample Nos. 27087–K, 61862–K.)
- Information Filed: September 26, 1950, Eastern District of Missouri, against John Frederick Borth, Jr., manager and pharmacist for Borth's Rexall Drug Store, Poplar Bluff, Mo.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of Missouri, of quantities of sulfadiazine and sodium bicarbonate tablets and thyroid tablets.
- ALLEGED VIOLATION: On or about January 9 and 11, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged sulfadiazine and sodium bicarbonate tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and the repackaged thyroid tablets failed to bear a label stating the place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), the repackaged sulfadiazine and sodium bicarbonate tablets bore no label containing the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (2), the repackaged sulfadiazine and sodium bicarbonate tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: March 27, 1951. A plea of guilty having been entered, the court imposed a fine of \$200 against the defendant.
- 3412. Misbranding of sulfadiazine tablets and Nembutal Sodium capsules. U. S. v. John Frederick Borth, Sr. Plea of guilty. Fine, \$200. (F. D. C. No. 29442. Sample Nos. 76521-K, 76545-K.)
- Information Filed: September 26, 1950, Eastern District of Missouri, against John Frederick Borth, Sr., manager of the Martin Drug Co., Poplar Bluff, Mo.
- INTERSTATE SHIPMENT: From the States of Tennessee and Illinois into the State of Missouri, of quantities of *sulfadiazine tablets* and *Nembutal Sodium capsules*.
- ALLEGED VIOLATION: On or about December 28, 1949, and January 10, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing statements of the quantity of the contents; Section 502 (f) (1), the repackaged drugs failed to bear adequate directions for use since the directions "One at bedtime as needed" borne on the labeling of the Nembutal Sodium capsules were not adequate directions for use and since the sulfadiazine tablets bore no labeling containing directions for use; and, Section 502 (b) (1), the repackaged sulfadiazine tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the Nembutal Sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged sulfadiazine tablets failed to bear a label containing the common or usual name of the tablets; and, Section 502 (f) (2), the repackaged sulfadiazine tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: March 27, 1951. A plea of guilty having been entered, the court imposed a fine of \$200 against the defendant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3413. Adulteration and misbranding of citrate of magnesia. U. S. v. 84 Cases

* * * (F. D. C. No. 30487. Sample No. 17091-L.)

LIBEL FILED: February 15, 1951, District of Arizona.

Alleged Shipment: On or about December 21, 1950, by the Pacific Coast Drug & Chemical Co., from Los Angeles, Calif.

PRODUCT: 84 cases, each containing 24 bottles, of citrate of magnesia at Phoenix, Ariz.

Label, IN Part: (Bottle) "Pasteurized Solution of Citrate of Magnesia U. S. P.

* * National Magnesia Co. Inc., Brooklyn, N. Y. Contents 340 CC."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Magnesium Citrate Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength was less than that which the standard set forth in such compendium since each 100 cc. contained magnesium citrate equal to not more than 1.4 gm. of MgO and contained not more than 8.02 gm. of total citric acid. The standard provides that magnesium citrate solution contains in each 100 cc. a sufficient amount of magnesium citrate to equal 1.6 gm. of MgO, and further provides that each 100 cc. of such solution shall contain not less than 9.10 gm. of total citric acid.

Misbranding, Section 502 (a), the label statement "Solution of Citrate of Magnesia U. S. P." was false and misleading as applied to an article which was not the U. S. P. product.

DISPOSITION: April 25, 1951. Default decree of condemnation and destruction.

959755--51----2

3414. Adulteration and misbranding of clinical thermometers. U. S. v. 48

* * (F. D. C. No. 29676. Sample No. 50866-K.)

LIBEL FILED: August 7, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about January 20 and April 28, 1950, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 48 clinical thermometers at Seattle, Wash. Examination of 24 thermometers showed that 5 failed to comply with the Commercial Standard CS1-42 since 3 failed to repeat readings and 2 did not give readings of the accuracy required by CS1-42.

LABEL, IN PART: (Package) "Cardinal DeLuxe Fever Thermometer."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess, namely, "* * * tested and found to meet all the requirements and tests specified in the United States Department of Commerce, Commercial Standard CS1-42 for Clinical Thermometers."

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which would not repeat readings or which did not give readings of the accuracy required by CS1-42: (Insert in package) "We, the undersigned Manufacturers, hereby certify that our registering clinical thermometer marked No... has been examined and tested and found to meet all the requirements and tests specified in the United States Department of Commerce, Commercial Standard CS1-42 for Clinical Thermometers. This certificate is supported by a record of test of this thermometer. * * The enclosed thermometer is guaranteed to be of absolute accuracy * * *."

DISPOSITION: April 30, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3415. Misbranding of Tran tablets. U. S. v. 57 Boxes, etc. (F. D. C. No. 30839. Sample Nos. 31366-L, 31556-L, 31557-L, 32151-L to 32153-L, incl., 32162-L, 32163-L.)

LIBEL FILED: March 12, 1951, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 15, 1950, and January 8, 9, 11, 12, and 22, 1951, by the Atlas Pharmaceutical Distributing Co., Inc., from Chicago, Ill.

Product: Tran tablets. 57 boxes of the \$15.00 size, 244 boxes of the \$6.00 size, and 574 boxes of the \$3.00 size, at St. Louis, Mo., in the possession of the Katz Drug Co., together with a placard entitled "Tran Relieves Pain of Arthritis and Rheumatism within 30 Minutes"; a cloth sign reading, in part, "You Need Tran - Safe - Sure - Guaranteed"; a number of paper strip signs reading, in part, "Stop Torturing, Stabbing, Burning, Pains"; a number of tear sheets of an advertisement, which appeared in a St. Louis paper, headed, in part, "Stop Your Pain"; and a number of counter display cards reading, in part, "Stop Pain."

^{*}See also Nos. 3413, 3414.

RESULTS OF INVESTIGATION: The cloth signs and the paper signs were shipped with the tablets. The placard had been prepared by the Katz Drug Co., and the tear sheets from the advertisement in the St. Louis newspaper were displayed on the dealer's premises. In addition, each box of the *Tran tablets* contained a 32-page booklet entitled "The Story of Arthritis and the New Wonder Drug that brings fast relief from Pain."

LABEL, IN PART: "Tran An Aid For The Relief Of Pain Due To [on some boxes "Simple"] Arthritis Rheumatism Bursitis * * * Two Brown Tablets Contain: 5 grs. Sodium Salicylate 2 grs. Calcium Succinate Each White Tablet Contains: 2 grs. Calcium Succinate 3 grs. Aspirin (Acetylsalicylic Acid) 20 mgm. Vitamin C (Ascorbic Acid)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the product was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce in that certain statements in the labeling, namely, the box label, the booklet, the paper signs, the placard, the cloth signs, the tear sheets, and the counter display cards, were false and misleading. These statements represented and suggested that the article was a drug containing new, amazing, wonder ingredients which made it an adequate and effective treatment for, and thus capable of curing or eliminating, arthritis, rheumatism, bursitis, rheumatic fever, infectious arthritis, allergic arthritis, gout, rheumatoid or atrophic arthritis, osteoarthritis, fibrositis, neuritis, neuralgia, excruciating pain, and pain generally; that it would stop torturing, stabbing, crippling, gnawing, burning pains of arthritis, rheumatism, bursitis, neuritis, neuralgia, sciatica, lumbago, sinusitis, and kindred aches and pains; that it would relieve sticking, stabbing, burning, twisting, gnawing pains of bones, joints, and muscles, due to rheumatism, neuralgia, arthritis, and kindred pains and torturing pains; that it would enable sufferers from unbearable pains of arthritis to do housework without any bother from arm and shoulder; that it would give relief from arthritis unobtainable from other medicinal preparations; that it would eliminate almost unbearable pains in arms, legs, shoulders, stomach muscles, and all over the body in five minutes; that it would relieve terrific aches and pains of arthritis; and that it would cause to vanish terrible aches and pains in the knees and the calves of the legs. The article was not a drug containing new, amazing, wonder ingredients; it was not effective for the purposes stated and implied; and it was not capable of fulfilling the promises of benefit made for it.

Disposition: April 5, 1951. Default decree of condemnation and destruction.

3416. Misbranding of Min-Ral tablets and Mino-Vites capsules. U. S. v. 285
Bottles, etc. (F. D. C. No. 30290. Sample Nos. 77945-K, 77946-K.)

LIBEL FILED: On or about December 8, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 26 and October 18, 1950, from Omaha, Nebr.

PRODUCT: 285 72-tablet bottles of *Min-Ral tablets* and 98 50-capsule bottles of *Mino-Vites capsules* at Lebanon, Mo., in possession of R. J. Christensen Co., together with a number of circulars entitled "Can You Stand Still Without "Wobbling" * * * Mino-Vites," "Better Health the Min-Ral Way," "Sick-Nervous-Never Well," and "If you were forced to starve to death."

RESULTS OF INVESTIGATION: The circulars were printed locally and were used to promote the sale of the products. The circulars were on display in the office beside the products or were on the wall.

LABEL, IN PART: (Bottle) "Min-Ral Salts 16 Minerals * * * Each tablet contains: Calcium 80.74 mgm., Phosphorus 62.5 mgm., Reduced Iron 10 mgm., Colloidal Copper 1.62 mgm., Magnesium 1.62 mgm., Zinc 0.1 mgm., Potassium 0.1 mgm., Tin 0.1 mgm., Manganese 0.1 mgm., Cobalt 0.1 mgm., Sodium 0.1 mgm., Nickel 0.1 mgm., Potassium Iodide 0.1 mgm., Sulphur 0.1 mgm., Aluminum 0.1 mgm., Boron 0.1 mgm."

(Bottle) "Mino-Vites *	* * Each Green	Capsule Contains:
$\mathbf{B_i}$	5 mgm. (500%)	*
B_2	5 mgm. (250%)	*
B_{6}	0.5 Mgm.	**
Calcium Pantothenate	10 Mgm.	**
Niacinamide U.S.P.	20 Mgm.	**
Vitamin B ₁₂	2 Mcgms.	**
Folic Acid	$0.25 \mathrm{Mgm}$.	**
With other B-Complex		
factors from liver		

Each Black Capsule Contains:

Iron	56.1 Milligrams (160%)	*
Calcium	187.0 Milligrams (23%)	*
Phosphorus	42.6 Mgm. (5%)	*
Iodine	15.0 Milligrams (100%)	*
Magnesium	7.2 Milligrams	**
Zinc	3.0 Milligrams	**
Copper	5.0 Milligrams	**
Sodium	2.5 Milligrams	**
Cobalt	0.33 Milligrams	**
Potassium	1.3 Milligrams	**
Manganese	4.08 Milligrams	**
Sulphur	Traces	
Liver	30.0 Milligrams	**

^{*}Percent Minimum Adult Daily Requirement.

NATURE OF CHARGE: Min-Ral tablets. Misbranding, Section 502 (a), certain statements in the circulars accompanying the article were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for stomach ailments, headaches, weak kidneys, nervousness, rheumatic complaints, acid toxins, arthritis, bloating, neuritis, anemia, lack of energy, poor appetite, sinus affections, underweight, conditions peculiar to the expectant mother and old people, many ailments of complicated doctor's diagnoses, ailments of long standing, aches and pains, kidney complaints, liver troubles, skin eruptions, tumors, cancer, bony infections, sexual disorders, eye, ear, nose, and throat troubles, nerve disorders, premature delivery in women, all kinds of heart ailments, common colds, ulcers, all types of anemia, and any and all of the human body ills; that the article would insure better health; that it would prevent death from infectious or noninfectious diseases; that it conformed to the requirements of Federal food and drug laws; that 99 percent of the American people are starving on full stomachs; that the article would relieve that "futile" feeling of despair of a premature death; that fruits, vegetables, and grains now being raised are so

^{**}The need in human nutrition has not been established."

deficient in needed minerals that people are starving no matter how much they eat; that fruits, vegetables, grains, eggs, milk, and meat of today are not what they were a few generations ago; that the basic remedy for sick stock is minerals; that the article was insurance for daily health; and that it was a life giving medicine, the activator of soil health, animal health, and human health. The article was not an adequate and effective treatment for the conditions stated and implied, and it would not fulfill the other promises of benefit set forth. Further misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading. The statements represented and suggested that the article contained 16 nutritionally useful minerals and that the need for manganese, zinc, aluminum, nickel, cobalt, tin, and boron in human nutrition has been established. The article did not contain 16 nutritionally useful minerals, and the need for the stated substances in human nutrition has not been established.

Mino-Vites capsules. Misbranding, Section 502 (a), certain statements in an accompanying circular were false and misleading. These statements represented and suggested that the article was effective for people who are never really well; that it was effective to prevent sickness, suffering, and shortening of the life span; and that it conformed to the Federal food and drug laws. The article was not effective for the purposes stated and implied, and it did not conform to the Federal food and drug laws. Further misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading. The statements represented and suggested that the article contained 12 nutritionally useful minerals; that the need in human nutrition for magnesium, copper, sodium, and liver constituents had not yet been established; that 56.1 milligrams of iron was 160 percent of the minimum adult daily requirement; and that 15 milligrams of iodine was 100 percent of the minimum adult daily requirement for those elements. The article did not contain 12 nutritionally useful minerals; the need in human nutrition for the stated constituents has been established; 56.1 milligrams of iron was not 160 percent of the minimum adult daily requirement; and 15 milligrams of iodine was not 100 percent of the minimum adult daily requirement for iodine.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 18, 1951. Default decree of destruction.

3417. Misbranding of Pro-Dyne Oral tablets, Pro-Dyne Oral capsules, Red-Zyne tablets, and Red-Zyne capsules. U. S. v. 89,380 Tablets, etc. (F. D. C. No. 29796. Sample Nos. 69429–K, 69430–K.)

LIBEL FILED: October 9, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 2, June 24, and August 16, 1950, by Food Essentials, Inc., from Chicago, Ill.

PRODUCT: 89,380 Pro-Dyne Oral tablets; 5 dozen 60-tablet bottles, 5½ dozen 120-tablet bottles, and 5 dozen 240-tablet bottles of Red-Zyne tablets; 60,380 Pro-Dyne Oral capsules; and 6½ dozen 30-capsule bottles, 3½ dozen 60-capsule bottles, and 2 dozen 120-capsule bottles of Red-Zyne capsules at Duquesne, Pa.

Accompanying the articles were 1,000 window streamers and 2,000 display placards entitled "Ask About Red-Zyne," 1,000 counter dodgers entitled "The New Red Magic Red-Zyne Capsules—Tablets," and 2,000 copies of a reprint from Red Book Magazine entitled "Red Magic for Millions."

RESULTS OF INVESTIGATION: The products were shipped in drums under the names *Pro-Dyne Oral tablets* and *Pro-Dyne Oral capsules*. After shipment, portions had been repacked under the names of *Red-Zyne tablets* and *Red-Zyne capsules*. The advertising material, streamers, placards, and dodgers, in the possession of the consignee, were for distribution to wholesale and retail outlets.

LABEL, IN PART: (Drums, when shipped) "Pro-Dyne Oral Tablets A Dietary Supplement Containing B₁₂ with other A. P. F. Factors from fermentation products B-Complex Vitamins and Minerals * * * Directions: As a dietary supplement: Two Tablets 3 times a day * * * Each Pro-Dyne Tablet supplies: * * * .2 mg. Boron (from Sod. Borate)" and "Pro-Dyne Oral Capsules A Dietary Supplement Containing B₁₂ with other A. P. F. Factors from fermentation products B-Complex Vitamins and Minerals * * * Directions: As a dietary supplement: One Capsule 3 times a day * * * Each Pro-Dyne Capsule supplies * * * .4 mg. Boron (from Sod. Borate)."

(Repackaged bottles) "Red-Zyne Tablets A Dietary Supplement Containing the New Red Vitamin B₁₂ with other A. P. F. Factors B-Complex Vitamins and Essential Minerals * * * Directions: Two Tablets 3 times a day * * * Each Red-Zyne Tablet Supplies: * * * .2 mg. Boron (from Sod. Borate)" and "Red-Zyne Capsules A Dietary Supplement Containing the New Red Vitamin B₁₂ with other A. P. F. Factors B-Complex Vitamins and Essential Minerals * * * Directions: As a dietary supplement One Capsule Three times a day * * * Each Red-Zyne Capsule Supplies: * * * .4 mg. Boron (from Sod. Borate)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the accompanying window streamers, display cards, and counter dodgers, and in the magazine reprints, were false and misleading. These statements represented and suggested that the articles when used as directed on the labels, would be efficacious in the treatment of nutritional anemia, pernicious anemia, secondary anemia, borderline anemia, and all other forms of anemia, fatigue, lack of appetite, poor health, nervousness, paleness, bronchitis, congestive heart failure, nausea, and sprue. The articles were not efficacious in the treatment of such conditions and diseases. The products were misbranded while held for sale after shipment in interstate commerce.

The products were also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 17249.

DISPOSITION: January 31, 1951. Default decree of condemnation and destruction.

3418. Misbranding of Peptotabs (Plus-Tabs). U. S. v. 243 Bottles * * * * (F. D. C. No. 30340. Sample No. 95630-K.)

LIBEL FILED: December 12, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 4, 1950, from New Brunswick, N. J. PRODUCT: 243 Bottles of *Peptotabs* (Plus-Tabs) at Philadelphia, Pa., in possession of the Darel Pharmacy, Philadelphia, Pa.

RESULTS OF INVESTIGATION: Placards which were entitled "Learn to Live Again," "Peptotabs strengthens the body," "A New You," and "Men * * * Women Over 40," and which related to the *Peptotabs*, were in the window of the Darel Pharmacy.

The product was sold also under the name "Plus-Tabs." A placard entitled "Are You Slipping" relating to the product "Plus-Tabs" was attached to the cash register in the store. When a customer would ask for "Plus-Tabs," the label from a bottle of *Peptotabs* was removed and a label for "Plus-Tabs" was placed thereon. The label of the "Plus-Tabs" was stated to be identical with that of the *Peptotabs*, except for the name of the product "Plus-Tabs" and the name of the distributor.

Label, IN Part: (Bottle) "100 Tablets Samson Peptotabs Each Tablet Containing: Ferrous Sulphate Exiccated, 3 gr.; Iron Peptonate, 1½ gr.; Manganese Glycerophosphate, ½ gr.; Calcium Glycerophosphate, 1 gr.; Lecithin, ¼ gr.; Thiamin Chloride 2.0 mg. * * * Distributed by Samson Drug Co. 126 N. 13th St., Phila. 7, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling accompanying the article were false and misleading since the article was incapable of fulfilling the promises of benefit stated and implied:

(Placard entitled "Learn to Live Again") "Learn To Live Again You'll take a New Lease on Life after Peptotabs Puts Plenty of Red Cells Into Your Blood Stream";

(Placard entitled "Peptotabs strengthens the body") "Peptotabs strengthens the body with rich red blood by increasing the natural production of healthly Blood Cells Only Peptotabs gives you this Special strengthening action";

(Placard entitled "A New You") "A New You if you don't feel like your onetime self Getting Old? No Vigor? No Pep? You owe it to yourself to take Peptotabs For sparkling up your Blood Action Don't delay—Buy Peptotabs today!";

(Placard entitled "Men * * * Women Over 40") "Men * * * Women Over 40 If you are listless feel out of sorts! Run Down and just can't get the energy to get started use Peptotabs To renew that Vim Vigor and Vitality Don't delay Buy today";

(Placard entitled "Are You Slipping") "Are you Slipping? Has middle age gotten you? Can't keep up? Tire easily? Try Plus-Tabs for Vim, Vigor and Vitality! Past 35? Feel Old? Get Pep, Vigor Are you losing that happy, carefree spirit of youth? Then do something about it. Don't let middle age drag you down and rob you of your cheerful disposition. Try Plus-Tabs, a remarkable tonic tablet made for men and women over 35. Results are so pleasant you will be reminded of your younger days. What a grand and glorious feeling to feel like yourself again."

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 28, 1951. Default decree of condemnation and destruction.

3419. Misbranding of alum. U. S. v. 33 Cartons * * * *. (F. D. C. No. 29514. Sample No. 68535-K.)

LIBEL FILED: August 4, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about May 4, 1950, by the Norton Products Co., from Los Angeles, Calif.

PRODUCT: 33 cartons, each containing 12 4-ounce packages, of alum at Seattle, Wash.

LABEL, IN PART: (Package) "Norco Alum USP Powdered Potassium Alum Net Wt. 4 Oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "As An Astringent Douche For Leucorrhea" was false and misleading since it suggested and implied that the article was effective in the treatment of leucorrhea, whereas the article was not effective for such purpose; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents (the article was short of the declared weight).

DISPOSITION: April 30, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3420. Misbranding of Tuttle's American Condition Powders. .U. S. v. 138
Boxes * * * (F. D. C. No. 30373. Sample No. 86630–K.)

LIBEL FILED: January 8, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about October 24, 1950, by the Tuttle's Elixir Co., from Boston, Mass.

PRODUCT: 138 boxes of Tuttle's American Condition Powders at Los Angeles, Calif.

LABEL, IN PART: (Box) "9 oz. when Packed Tuttle's American Condition Powders Keep Your Horse in Good Condition * * * Fabricated from the Following Ingredients Charcoal, African Ginger, Iron Sulphate, Gentian Root, Quassia Chips, Magnesium Sulphate, Fenugreek, Fennel, Soda Bicarbonate, Elm Bark, Yellow Bark, Sulphur, Salt, Salt-Petre, Middlings."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective for the purposes stated and implied: "* * * Condition Powders Keep Your Horse in Good Condition * * * When horse is thin and appetite is not improving, double the dose, morning and night * * * Condition Powders Used for All Forms of Indigestion. It increases the digestive fluids in the stomach. It assists peristalsis action of the intestines, thereby being a resistant to digestive disturbances. It enriches the blood and serves to keep the blood stream through the different organs of the body in proper tolerance. It can be profitably used in connection with the following conditions:—Loss of appetite, improvement of the skin and coat, overwork, exhaustion, nervousness, overfeeding, urinary troubles, inorganic conditions of the kidney and urinary organs, is an assurance against cholic, and will regulate the bowels. Incapacities resulting from impaired digestion will be prevented by the timely use of Tuttle's American Condition Powders, and is useful in the convalescent stages of other diseases arising from indigestion."

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents (the article was short of the declared weight); and, Section 502 (c), the information required by law to appear upon the label, namely, the names of the active ingredients of the article, was not placed thereon with such conspicuousness and in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since the names of such active ingredients were interspersed among the names of inert ingredients.

Disposition: February 14, 1951. Default decree of condemnation and destruction.

959755—51——3

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3401 TO 3420

PRODUCTS

	J. No.		J. No.
ACTH	3401	Phenobarbital tablets 3402	3403
Alum	3419	Plus-Tabs. See Peptotabs.	
Amphetamine hydrochloride		Pro-Dyne Oral tablets and Pro-	
tablets	3407	Dyne Oral capsules	3417
Amytal tablets	3410	Red-Zyne tablets and Red-Zyne	
Arthritis, remedy for	3415	capsules	3417
Benzedrine Sulfate tablets	3408	Rheumatism, remedy for	3415
Citrate of magnesia	3413	Seconal Sodium capsules 3406	3407
Clinical thermometers	3414	Sulfadiazine tablets	3412
Combisul-TD tablets	3408	and sodium bicarbonate	
Desoxyn Hydrochloride tablets	3408	tablets 3410	. 3411
Devices	3414	Sulfathiazole tablets 3404	
Dexedrine Sulfate tablets_ 3403-		Thermometers, clinical	3414
Dextro-amphetamine phosphate	0100	Thyroid tablets 3409	
tablets	3409	Tran tablets	3415
Diethylstilbestrol tablets 3408-		Triple sulfa tablets	3409
Leucorrhea, remedy for	3419	Tuinal capsules	3402
Magnesia, citrate of	3413	Tuttle's American Condition	3402
	3416		2400
Mino-Vites capsules		Powders	3420
Min-Ral tablets	3416	Veterinary preparation	3420
Nembutal Sodium capsules	3412	Vitamin preparations	3416
Pentobarbital sodium capsules	3406	Women's disorders, remedies	
Peptotabs (Plus-Tabs)	3418	for	3419
SHIPPERS MANUEA	CTUR	ERS, AND DISTRIBUTORS	
SHILL DIES, MINICOLD		no, mo pismiberons	
N.	J. No.	N.	J. No.
Atlas Pharmaceutical Distribu-		Borth's Rexall Drug Store:	
ting Co., Inc.:		sulfadiazine and sodium bicar-	
Tran tablets	3415	bonate tablets and thyroid	
Belmont Pharmacy. See Storms,		tablets	3411
J. R.		Bowron, D. A.:	
Berger, J. C.:		Benzedrine Sulfate tablets,	
Benzedrine Sulfate tablets,		Combisul-TD tablets, di-	
Combisul-TD tablets, diethyl-		ethylstilbestrol tablets, and	
stilbestrol tablets, and De-		Desoxyn Hydrochloride tab-	
soxyn Hydrochloride tablets_	3408	lets	3408
Biological Derivatives, Inc.:		Bradley's Drug Store, Inc.:	010
ACTH	3401	Tuinal capsules and pheno-	
Borth, J. F., Jr.:	0101	barbital tablets	3402
sulfadiazine and sodium bicar-		Bristol Drug Corp.:	0102
bonate tablets and thyroid		pentobarbital sodium capsules	
· ·	3411	and Seconal Sodium capsules	3406
Borth, J. F., Sr.:	OTIL	Burnett, R. B.:	9400
sulfadiazine tablets and Nem-		phenobarbital tablets and Dexe-	
butal Sodium capsules	3412	drine Sulfate tablets	3403
bual Soulum Capsules	0417	urine surrate tablets	0.400

N.	J. No.	N.	J. No.
Cardinal Thermometer Co.:		National Magnesia Co., Inc.:	
clinical thermometers	3414	citrate of magnesia	3413
Christensen, R. J., Co.:		Norton Products Co.:	
Min-Ral tablets and Mino-		alum	3419
Vites capsules	3416	Pacific Coast Drug & Chemical	
Darel Pharmacy:		Co.:	
Peptotabs (Plus-Tabs)	3418	citrate of magnesia	3413
Drug Center. See McGaughey,		Pinard, K. L.:	
Н. Е.		Dexedrine Sulfate tablets	3405
East Side Pharmacy:		Pinard Drug Co. See Pinard,	
Dexedrine Sulfate tablets and		K. L.	
sulfathiazole tablets	3404	Princeton Laboratory Products	
Food Essentials, Inc.:		Co.:	
Pro-Dyne Oral tablets, Pro-		ACTH	3401
Dyne Oral capsules, Red-		Samson Drug Co.:	
Zyne tablets, and Red-Zyne		Peptotabs (Plus-Tabs)	3418
capsules	3417	Seybold Drug Co.:	
Katz Drug Co.:		thyroid tablets, diethylstilbes-	1
Tran tablets	3415	trol tablets, Amytal tablets,	
McGaughey, H. E.:		sulfadiazine and sodium bi-	
thyroid tablets, dextroamphet-		carbonate tablets, and sulfa-	
amine phosphate tablets,		thiazole tablets	3410
triple sulfa tablets, and di-		Smith's of Spartanburg, Inc.:	
ethylstilbestrol tablets	3409	phenobarbital tablets and Dex-	
Martin Drug Co.:		edrine Sulfate tablets	3403
sulfadiazine tablets and Nem-		Storms, J. R.:	
butal Sodium capsules	3412	Seconal Sodium capsules and	
Miller, H. W., Drug Co.:		amphetamine hydrochloride	
Benzedrine Sulfate tablets,		tablets	3407
Combisul-TD tablets, diethyl-		Tuttle's Elixir Co.:	
stilbestrol tablets, and De-		Tuttle's American Condition	7110
soxyn Hydrochloride tablets_	3408	Powders	3420

INTERNATIONAL PROPERTY

the Princes Server of American con-

1000

1

1000

.....

A SOUTH THE PARTY OF THE PARTY

batte (1. c) and a finite of the control of the con

no in Ga

Jennie og 15 17.



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3421-3440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs.

Washington, D. C., September 26, 1951.

CONTENTS*

	Page		Page
Drugs actionable because of failure		Drugs and devices actionable be-	
to bear adequate directions or		cause of false and misleading	
warning statements	410	claims	418
Drugs for human use	410	Drugs for human use	418
Drugs for veterinary use	415	Drug for veterinary use	429
Drugs actionable because of con-		Drug actionable because of failure	
tamination with filth	416	to comply with packaging re-	
Drugs and devices actionable be-		quirements of an official com-	
cause of deviation from official		pendium	430
or own standards	417	Index	430

^{*}For presence of a habit-forming narcotic without warning statement, see No. 3423; omission of, or unsatisfactory, ingredients statements, Nos. 3422, 3424-3427, 3429; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3422-3427, 3429, 3440; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3422, 3423, 3425-3427, 3429, 3440.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

3421. Misbranding of Estinyl tablets, Hormotone "T" tablets, Oreton-M tablets, Neo-Hombreol tablets, and Metandren Linguets. U. S. v. Ace Mail Order Co. and Mendel Bernstein. Pleas of nolo contendere. Each defendant fined \$750. (F. D. C. No. 29421. Sample Nos. 4737–K, 19885–K, 19898–K, 19893–K to 19895–K, incl.)

Information Filed: June 27, 1950, District of New Jersey, against the Ace Mail Order Co., a partnership, East Orange, N. J., and Mendel'Bernstein, a partner in the firm.

ALLEGED SHIPMENT: On or about June 2 and 24 and July 11, 1949, from the State of New Jersey into the States of Massachusetts and Tennessee.

LABEL, IN PART: "Schering Tablets Estinyl * * * Brand of Ethinyl Estradiol * * * Each tablet contains 0.05 mg. Crystalline Pure Ethinyl Estradiol Schering Corporation Bloomfield, New Jersey," "Schering Estinyl tablets .05 m. g.," "Hormotone "T Estrogenic Hormones * * * Each tablet contains estrogens (estradiol, estrone) equivalent to 1,000 International Units and ½0 gr. thyroid * * * G. W. Carnrick Co. Newark, N. J.," "Schering Oreton-M * * * Brand of Methyl Testosterone Crystalline pure testicular hormone preparation * * * Schering Corporation Bloomfield, New Jersey * * Each tablet contains 10 mg. Methyl Testosterone," "Tablets 10 mg. each Neo-Hombreol (M) 'Roche-Organon' * * (Androgenic Preparation—Brand of Methyl Testosterone) * * * Roche-Organon, Inc. Nutley, New Jersey Organon, Inc. Formerly known as Roche-Organon, Inc. Orange, New Jersey," and "Metandren Linguets Brand of Methyltestosterone U. S. P. * * * 10 mg. * * * Ciba Pharmaceutical Products, Inc. Summit, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the labeling bore no directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users. The labeling of the *Estinyl tablets* failed to warn that their use by the male may result in sterility and loss of sexual power and may have a feminizing effect upon the male; that their use by the female may result in sterility, injury to the female generative system, and bleeding from the uterus; and that their use by females with carcinoma of the breast, cervix, and uterus may result in acceleration of malignant growth. The labeling of the *Hormotone "T" tablets* bore no warnings against unsafe dosage and duration of administration. The labeling of the *Oreton-M tablets*, *Neo-Hombreol tablets*, and *Metandren Linguets* failed to warn that the use of such tablets and linguets may result in sterility and that their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: March 30, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$750 against each defendant.

- 3422. Misbranding of methyltestosterone tablets, Dexedrine Sulfate tablets, and amphetamine sulfate tablets. U. S. v. The Brant Building Pharmacy Co. (Physicians Pharmacy), Louis Weiner, and Edward Vogler. Pleas of guilty. Fine of \$200, plus costs, against company; fine of \$100 against Louis Weiner, and \$50 against Edward Vogler. (F. D. C. No. 30022. Sample Nos. 52473-K, 72179-K, 72225-K, 72242-K, 72418-K.)
- INFORMATION FILED: April 2, 1951, Northern District of Ohio, against The Brant Building Pharmacy Co., a corporation, trading as Physicians Pharmacy, Canton, Ohio; Louis Weiner, president and treasurer of the corporation; and Edward Vogler, pharmacist for the corporation.
- Interstate Shipment: From the States of New Jersey, Pennsylvania, and New York, into the State of Ohio, of quantities of methyltestosterone tablets, Dexedrine Sulfate tablets, and amphetamine sulfate tablets.
- ALLEGED VIOLATION: On or about December 17, 1949, and January 13, February 21, and March 25, 1950, while the drugs were being held for sale at The Brant Building Pharmacy Co. after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

The Brant Building Pharmacy Co. and Louis Weiner were charged with causing the acts of repacking and sale of the drugs involved in each of the 5 counts of the information; and, in addition, Edward Vogler was charged in 2 of the counts with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged amphetamine sulfate tablets and a portion of the repackaged Dexedrine Sulfate tablets bore no labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (1), all of the repackaged Dexedrine Sulfate tablets and amphetamine sulfate tablets failed to bear labels containing the common or usual name of the drugs.

- Disposition: April 13, 1951. Pleas of guilty having been entered, the court imposed a fine of \$200, plus costs, against the corporation, a fine of \$100 against Louis Weiner, and a fine of \$50 against Edward Vogler.
- 3423. Misbranding of phenobarbital tablets and Dexedrine Sulfate tablets. U. S. v. Smith's Inc., Harry J. Crow, John K. Robertson, and Benjamin F. Talbert. Pleas of nolo contendere. Corporation fined \$100; each individual fined \$25 and placed on probation for 5 years. (F. D. C. No. 30041. Sample Nos. 81983-K, 81984-K, 81986-K, 81987-K, 81995-K, 81997₅-K.)
- Information Filed: February 21, 1951, Western District of South Carolina, against Smith's, Inc., a corporation, Spartanburg, S. C., and against Harry J. Crow, vice president, and John K. Robertson and Benjamin F. Talbert, pharmacists for the corporation.
- Interstate Shipment: From the States of Georgia and Pennsylvania into the State of South Carolina, of quantities of *phenobarbital tablets* and *Dexedrine Sulfate tablets*.
- ALLEGED VIOLATION: On or about July 13 and 20 and August 9, 1950, while the drugs were being held for sale at Smith's, Inc., after shipment in interstate

commerce, various quantities of the tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

Smith's, Inc., was charged with causing the acts of repacking and sale of the drugs involved in each of the six counts of the information; and, in addition, Harry J. Crow in two of the counts, John K. Robertson in two of the counts, and Benjamin F. Talbert in the remaining two counts of the information were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor, and no labels containing statements of the quantity of the contents; and Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

- DISPOSITION: April 5, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against the corporation and a fine of \$25 against each individual and placed the individuals on probation for 5 years.
- 3424. Misbranding of Combisul tablets, Dexedrine Sulfate tablets, and Desoxyn Hydrochloride tablets. U. S. v. Ralph G. Garner, Jr. (Garner Pharmacy), Forrest R. Gill, and Robert Hartman. Pleas of guilty. Fine of \$300 against Defendant Garner, \$150 against Defendant Gill, and \$75 against Defendant Hartman. (F. D. C. No. 30564. Sample Nos. 72145-K, 72813-K, 84434-K.)
- Information Filed: Between March 15 and April 13, 1951, Southern District of Ohio, against Ralph G. Garner, Jr., trading as the Garner Pharmacy, Columbus, Ohio, and against Forrest R. Gill, an employee, and Robert Hartman, a pharmacist, for Mr. Garner.
- INTERSTATE SHIPMENT: From the States of New Jersey, Pennsylvania, and Illinois, into the State of Ohio, of quantities of Combisul tablets, Dexedrine Sulfate tablets, and Desoxyn hydrochloride tablets.
- ALLEGED VIOLATION: On or about June 27, 28, and 30, 1950, while the drugs were being held for sale at the Garner Pharmacy after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Ralph G. Garner, Jr., was charged with causing the acts of repacking and sale of the drugs involved in each of the three counts of the information; and, in addition, Forrest R. Gill in two of the counts and Robert Hartman in one of the counts of the information were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE of CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (2), the repackaged Dexedrine Sulfate tablets and Combisul tablets failed to bear labels containing a statement of the quantity of the contents; Section 502 (e) (2), the repackaged Combisul tablets were fabricated from two or more ingredients and failed to bear a

- label containing the common or usual name of each active ingredient, namely, sulfadiazine and sulfathiazole; and, Section 502 (f) (2), the labeling of the repackaged *Desoxyn Hydrochloride tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- DISPOSITION: May 4, 1951. Pleas of guilty having been entered, the court imposed a fine of \$300 against Defendant Garner, a fine of \$150 against Defendant Gill, and a fine of \$75 against Defendant Hartman.
- 3425. Misbranding of sulfadiazine tablets, Desoxyn Hydrochloride tablets, and thyroid tablets. U. S. v. The Sloan Drug Co., Theodore J. Schlonsky, and Harry Wolman. Pleas of guilty. Fine of \$300 against company, \$225 against Defendant Schlonsky, and \$150 against Defendant Wolman. (F. D. C. No. 30573. Sample Nos. 84423-K, 84424-K, 84427-K.)
- INFORMATION FILED: Between April 20 and May 4, 1951, Southern District of Ohio, against The Sloan Drug Co., a corporation, Columbus, Ohio, and Theodore J. Schlonsky, secretary of the corporation, and Harry Wolman, pharmacist for the corporation.
- INTERSTATE SHIPMENT: From the States of Indiana, Illinois, and New York, into the State of Ohio, of quantities of sulfadiazine tablets, Desoxyn Hydrochloride tablets, and thyroid tablets.
- ALLEGED VIOLATION: On or about June 13, 15, and 20, 1950, while the drugs were being held for sale at The Sloan Drug Co. after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

The Sloan Drug Co. and Theodore J. Schlonsky were charged with causing the acts of repacking and sale of the drugs involved in each of the three counts of the information; and, in addition, Harry Wolman was charged in two of the counts with causing such acts to be done in connection with the drugs involved in those counts.

- Nature of Charge: Misbranding, Section 502 (b) (1), the repackaged sulfadiazine tablets and Desoxyn Hydrochloride tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; Section 502 (e) (1), the repackaged sulfadiazine tablets and Desoxyn Hydrochloride tablets failed to bear labels containing the common or usual names of the drugs; Section 502 (f) (1), the repackaged Desoxyn Hydrochloride tablets and thyroid tablets failed to bear labeling containing directions for use; and, Section 502 (f) (2), the repackaged sulfadiazine tablets and Desoxyn Hydrochloride tablets failed to bear labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- Disposition: May 4, 1951. Pleas of guilty having been entered, the court imposed a fine of \$300 against the corporation, a fine of \$225 against Defendant Schlonsky, and a fine of \$150 against Defendant Wolman.
- 3426. Misbranding of sulfathiazole tablets and Combisul tablets. U. S. v. The Poulston Drug Co. and Harry D. Poulston. Pleas of nolo contendere. Fine of \$100 against each defendant, plus costs. (F. D. C. No. 30043. Sample Nos. 52968–K, 72840–K, 84162–K, 84938–K, 84961–K.)

Information Filed: February 27, 1951, Northern District of Ohio, against The Poulston Drug Co., a corporation, Lima, Ohio, and Harry D. Poulston, president of the corporation.

INTERSTATE SHIPMENT: From the State of Indiana into the State of Ohio, of quantities of sulfathiazole tablets and Combisul tablets.

ALLEGED VIOLATION: On or about April 21, June 23, and August 8, 11, and 25, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

Nature of Charge: Repackaged sulfathiazole tablets. Misbranding, Sections 502 (b) (1) and (2), the tablets failed to bear the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), a portion of the tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Repackaged *Combisul tablets*. Misbranding, Section 502 (b) (2), the label of the tablets bore no statement of the quantity of the contents; Section 502 (e) (2), the tablets bore no label containing the common or usual name of each active ingredient of the tablets, namely, sulfadiazine and sulfathiazole; and Section 502 (f) (1), the labeling of the tablets bore no directions for use.

Disposition: April 5, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against each defendant, plus costs.

3427. Adulteration and misbranding of Premarin tablets. U. S. v. 2,000 Tablets * * * (F. D. C. No. 30841. Sample No. 23101–L.)

LIBEL FILED: February 19, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about July 15, 1950, by Max Lippmann, from New York, N. Y. The tablets were supplied in a plain paper bag by Sol Lederman, New York, N. Y., to Mr. Lippmann, who transported them in his personally owned vehicle.

Product: 2,000 Premarin tablets at Paterson, N. J. Each tablet was represented to contain 1.25 mg. of Premarin, a brand name for water-soluble, conjugated estrogens derived from pregnant mares' urine. Examination showed that most of the tablets contained no water-soluble, conjugated estrogens derived from pregnant mares' urine.

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of Premarin per tablet.

Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the label of the article failed to bear adequate directions for use.

DISPOSITION: April 24, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

- 3428. Misbranding of Sal-Trag Compound. U. S. v. 12 Cases * * *. (F. D. C. No. 25267. Sample No. 31621–K.)
- LIBEL FILED: August 11, 1948, Southern District of California.
- ALLEGED SHIPMENT: On or about June 15, 1948, by Research Laboratories, Inc., from Portland, Oreg.
- PRODUCT: 12 cases, each containing 12 1-pint bottles, of Sal-Trag Compound at Los Angeles, Calif.
- LABEL, IN PART: "Sal-Trag Compound Active Ingredients. An Aqueous Extraction Of The Following Botanicals: Plume Thistle * * * Burdock * * * Sage * * * Kola * * * Dandelion * * * Horehound * * * Calamus * * * Althea * * * Quassia * * * Cinnamon * * * Ginseng * * * Sodium Benzoate. Cascara Sagrada and Licorice Added."
- Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the only directions appearing in the labeling, namely, "Two teaspoonfuls before each meal and four teaspoonfuls before retiring at night or as directed," were inadequate in that such directions failed to reveal the diseases or conditions of the body for which the article, when used as directed, would be effective.
- DISPOSITION: February 7, 1951. Research Laboratories, Inc., having appeared as claimant, and the case having been removed to the Northern District of Illinois and the claimant having subsequently consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS FOR VETERINARY USE

- 3429. Misbranding of mineral solution. U. S. v. 11 Barrels, etc. (F. D. C. No. 30383. Sample No. 93206-K.)
- LIBEL FILED: January 25, 1951, Southern District of Florida.
- ALLEGED SHIPMENT: On or about September 25, 1950, by Thomas Eason, from Bay Springs, Miss.
- PRODUCT: 11 unlabeled 50-gallon barrels of *mineral solution* at St. Petersburg, Fla., in possession of Southern Minerals, Inc., together with a number of pieces of printed matter intended for use as labels on retail bottles of the product and a number of circulars entitled "It's A Problem."
- Results of Investigation: The circulars were prepared under the direction of Jesse Green, president of Southern Minerals, Inc., and were approved by both him and his son, Carl Green. The wording of the printed matter intended for use as labels on the product was directed by both Jesse Green and Carl Green. Such printed matter contained, among other things, the following statements: "Original Liquid Mineral Food * * * A mineral solution containing sulphates, phosphates and Chlorides of Iron, Calcium, Magnesium, Aluminum, Nickel, Manganese, Copper, Sodium, Potassium and Cobalt."
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling failed to bear adequate directions for use. The article was misbranded in the above respects when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (a), certain statements in the printed matter intended for use as labels were false and misleading. These statements represented and suggested that the article was bacteriostatic; that it was effective as a vermifuge; and that it was effective in bringing about and maintaining a state of health and vitality in poultry. The article was not bacteriostatic, and it was not effective for the purposes represented. Further misbranding, Section 502 (a), certain statements in the accompanying circulars which represented and suggested that the article was effective in keeping animals healthy and free from sickness and as a treatment for really sick animals; that it was effective to increase the appetite; that it would hasten the growth of cattle, maintain body health, and regulate digestion; that it was effective to build stronger, heavier bones; that it was effective to give better distribution of fat and to give finish to ranch, dairy, and farm animals; that vitamins are compounded within the bodies of plants and animals from the minerals contained in the foods consumed by them; and that due to depletion of the mineral content of our lands, the grasses and grains no longer contain minerals in quantities sufficient to nourish animals and produce top quality, were false and misleading. The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce.

DISPOSITION: March 8, 1951. Southern Minerals, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3430. Misbranding of phenothiazine drench. U. S. v. 1 Drum * * * (F. D. C. No. 30790. Sample No. 522–L.)

LIBEL FILED: On or about March 27, 1951, District of Kansas.

ALLEGED SHIPMENT: On or about January 9, 1951, by the Thompson-Hayward Chemical Co., from Kansas City, Mo.

PRODUCT: 1 drum containing 150 pounds of phenothiazine drench at Girard, Kans.

Label, In Part: "Phenothiazine Drench * * * From Atomic Basic Chemicals Corporation * * * Pittsburgh, Pa."

Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling bore no directions for use; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 3, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3431. Adulteration of burdock root, cocillana bark, jalap root, and white squill.

U. S. v. 11 Bags, etc. (F. D. C. No. 28685. Sample Nos. 10085-K, 10087-K to 10089-K, incl.)

LIBEL FILED: January 11, 1950, Eastern District of New York.

ALLEGED SHIPMENT: During 1942, on or about December 12, 1946, and November 18, 1947, and during June 1949, from various foreign countries.

PRODUCT: 11 110-pound bags of burdock root, 422 100-pound bales of cocillana bark, 16 160-pound bags of jalap root, and 160 60-pound bags of white squill at Brooklyn, N. Y., in possession of R. J. Prentiss & Co., Inc.

Nature of Charge: Adulteration, Section 501 (a) (1), the articles consisted in part of filthy substances by reason of the presence of insects, and the cocillana bark consisted also in part of a decomposed substance by reason of the presence of mold; and, Section 501 (a) (2), the articles had been held under insanitary conditions whereby they may have become contaminated with filth. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 27, 1950. R. J. Prentiss & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for segregation and destruction of the unfit portions, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruction of 693 pounds of jalar root, 1,112 pounds of white squill, and the entire lots of burdock root and cocillana bark.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3432. Adulteration and misbranding of Biotropin. U. S. v. 126 Vials * * *. (F. D. C. No. 29568. Sample No. 78426-K.)

Libel Filed: On or about September 8, 1950, Western District of Washington.

Alleged Shipment: On or about April 25, 1950, from Los Angeles, Calif.

PRODUCT: 126 10-cc. vials of *Biotropin* at Seattle, Wash. Examination showed that the product contained materially less than 3,000 M. U. (mouse units) of pituitary gonadotropins per vial.

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 3,000 mouse units of pituitary gonadotropins per vial.

Misbranding, Section 502 (a), the label statement "Ovine Pituitary Gonadotrophins * * * 3,000 M. U. Per Vial" was false and misleading as applied to an article which contained materially less than 3,000 mouse units of pituitary gonadotropins per vial.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 30, 1951. Default decree of condemnation and destruction.

3433. Adulteration and misbranding of clinical thermometers. U. S. v. 120 * * * (F. D. C. No. 30903. Sample No. 30851-L.)

LIBEL FILED: April 5, 1951, Eastern District of Missouri.

Alleged Shipment: On or about January 11, 1951, by the Ideal Thermometer Co., Inc., from Brooklyn, N. Y.

^{*}See also No. 3427.

Product: 120 clinical thermometers at St. Louis, Mo. Examination of 24 thermometers taken from the shipment showed one which failed to repeat readings, two which failed to meet the test for retreating index, and one with engraved markings wider than the intervening spaces.

LABEL, IN PART: "Colorfast Brand Clinical Thermometers Oral."

Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statement which appeared in the labeling of the article "We, as manufacturers, hereby certify that the enclosed clinical thermometer No. _____ has been manufactured in strict accordance with the Clinical Thermometer Commercial Standard No. CS-1-42, Bureau of Standards, Washington, D. C." was false and misleading since the device did not comply with the Bureau of Standards' Commercial Standard No. CS 1-42.

DISPOSITION: May 2, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3434. Misbranding of Brown's powdered goat milk. U. S. v. 607 Cases, etc. (F. D. C. No. 30819. Sample No. 18840-L.)

LIBEL FILED: February 26, 1951, Western District of Wisconsin.

ALLEGED SHIPMENT: Between May 12, 1948, and October 16, 1950, from Stillwater, Minn., by Arthur G. Brown and his wife, Mrs. Della T. Brown.

Product: 1,057 cases, each containing 24 1-pound tins, 15 cases, each containing 12 1-pound tins, and 16 cases, each containing 6 1-pound tins, of Brown's powdered goat milk at Menomonie, Wis., in the possession of Mrs. Della T. Brown, together with a number of mimeographed sheets entitled "Brown's Powdered Whole Goat Milk," a number of cards entitled "Brown's Powdered Goat Milk," and a number of mimeographed sheets entitled "Chemical Elements in Goat Milk."

Label, In Part: (Portion) "Brown's Powdered Goat Milk * * * Fortified with Vitamin D_2 ."

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements on the mimeographed sheets and cards were false and misleading. The statements represented and suggested that the article was effective in the treatment of asthma, hay fever, arthritis, neuritis, stomach ulcers, chronic irregularities, digestive troubles, eczema, and other skin diseases; that it had germicidal properties and was healing to wounds and injured parts; that it was useful for brain building; that it would feed the brain; and that consumption of the article would lead to health, peace, and prosperity. The article was not effective for the purposes stated and implied, and it was not capable of fulfilling the promises of benefit made for it. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 16, 1951. Mrs. Della T. Brown, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

^{*}See also Nos. 3432, 3433.

3435. Misbranding of Tates Antiseptic Germicide. U. S. v. 10 Cases * * * *. (F. D. C. No. 29101. Sample No. 35866-K.)

LIBEL FILED: May 9, 1950, District of Hawaii.

ALLEGED SHIPMENT: On or about January 4, 1950, by Tate Chemical Co., Inc., San Jose, Calif.

PRODUCT: 10 cases, each containing 12 6-ounce bottles, of *Tates Antiseptic Germicide* at Honolulu, T. H. Analysis showed that the product consisted essentially of epsom salt, zinc sulfate, boric acid, a salicylate, water, and acetone.

Nature of Charge: Misbranding, Section 502 (a), the following statements in the labeling of the article, namely, in the leaflets wrapped around each bottle, were false and misleading since the article was not an adequate and effective treatment for the conditions stated and implied: "This product has been found exceptionally efficacious in treatment of some of the most contagious skin troubles and other ills. Among these we list those we claim this antisepticgermicide will rapidly and almost always permanently relieve: * * * ber's itch, blackheads, blood poison, burns, scalds, erysipelas, eczema, * * * hives, itching scalp, itching piles, * * * old sores * * * acne, ring worm, shingles, salt rheum, seven-year itch, doby itch, skin scale * * *. It also has been used successfully in combating the distress of foul smelling feet by remedying the cause. Burns and Scalds These are naturally not caused by germs. Even the chemist that perfected this preparation is unable to explain how it acts in relieving the pain caused by burns, scalds * * *. If applied immediately, it will prevent blistering * * * So many human ailments are declared to be due to germs, that the discovery of a formula that kills germs with such remarkable thoroughness, means a great deal to humanity. The fact that germs or bacteria are regarded as the cause of almost every known contagious disease or infection, makes it particularly gratifying that this antiseptic-germicide was created after many years of intensive study, experiment and tests by Dr. Tate."

DISPOSITION: April 3, 1951. Tate Chemical Co., Inc., having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3436. Misbranding of Vrilium Catalytic Barium Chloride tube. U. S. v. Vrilium Products Co., George C. Erickson, and Robert T. Nelson, Jr. Pleas of not guilty. Tried to the court and jury. Verdict of guilty. Fines of \$1,000 against each defendant, plus costs; each individual defendant also sentenced to 1 year in prison. Judgment affirmed on appeal (185 F 2d 3). Petition for certiorari denied by U. S. Supreme Court (340 U. S. 947). (F. D. C. No. 21428. Sample Nos. 14616-H, 17656-H.)

Information Filed: January 20, 1947, Northern District of Illinois, against the Vrilium Products Co., a corporation, and George C. Erickson, president, and Robert T. Nelson, Jr., vice-president, of the corporation.

ALLEGED SHIPMENT: On or about June 25, 1945, from the State of Illinois into the State of Michigan.

PRODUCT: Examination showed that the device was not radioactive. The device consisted of a small glass tube sealed at both ends and containing a white crystalline substance. The glass tube was encased in a thin, pencil-shaped brass tube 1½ to 2 inches long.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "General Directions," which accompanied the device, were false and misleading. The statements represented and suggested that the device would be effective in giving forth emanations having physiological value and that the device would be effective in the treatment of conditions involving the sinuses, bronchial tubes, thyroid, low red blood corpuscle count, injuries, burns, and illness in general. The device would not be effective for such purposes.

DISPOSITION: Following the entry of pleas of not guilty on April 12, 1948, counsel for the defendants filed motions to quash and to dismiss the information, which motions were denied. Trial of the case began before the court and a jury on March 20, 1950; and at its conclusion on April 5, 1950, the court gave the following instructions to the jury:

INSTRUCTIONS TO THE JURY

LABUY, District Judge: "Ladies and Gentlemen of the Jury, the Court will now instruct you as to the law which you are to apply in this case. I suggest you follow these instructions carefully because you will not have them with

you in the jury room. So please pay close attention.

"This prosecution arises under the Federal Food, Drug, and Cosmetic Act. The purpose of the Act is to protect the public health and welfare. It is designed to require that purchasers be truthfully and accurately informed of what they are buying. Thus the law touches phases of lives and health of people that are largely beyond self-protection. This case was begun by an information in which the United States Attorney charged the defendants, Vrilium Products Company, a corporation, George C. Erickson, and Robert T. Nelson, Jr., individuals, with having made an interstate shipment of one carton containing a number of tubes known as 'Vrilium Catalytic Barium Chloride,' a device within the meaning of the Act. The device is alleged to have been misbranded by reason of statements made in the labeling of the device. It is alleged that statements in the labeling were false and misleading. The Government asserts that the defendants unlawfully caused to be introduced and delivered for introduction into interstate commerce a device which was misbranded. This the defendants deny. The Government asserts that accompanying the device when shipped in interstate commerce by defendants was a printed leaflet, which contained false and misleading statements. This the defendants also deny. The Government asserts that the device when shipped by the defendants in interstate commerce was misbranded in that the labeling was false and misleading because statements in the leaflet represented and suggested and created in the mind of the reader the impression that the device would be effective in giving forth emanations of a physiological value and that the device would be effective in the treatment of conditions involving the sinuses, bronchial tubes, thyroid, low red corpuscle count, injuries, burns, and illness in general; whereas, in fact and in truth, the device would not give forth emanations having physiological value or be effective in the treatment of the conditions already named. This the defendants also deny.

"There are two broad general questions involved in this case regarding which you will be required to concern yourselves. The first one pertains to the interstate commerce phase. In that regard the Government has charged the devices accompanied by a label and leaflets were shipped in interstate commerce from Chicago, Illinois, to Wyandotte, Michigan. You will have to decide whether the devices and labeling were so shipped. If you find that the devices and labeling were not shipped from Chicago to Wyandotte, Michigan, then it will be necessary for you to return a verdict of not guilty for all the defendants. If you decide the devices and labeling were shipped from Chicago to Michigan, for your second consideration, it will then be necessary for you to détermine whether or not the labels and leaflets contained a false or misleading statement. If you decide that the devices and labeling were shipped from Chicago to Michigan, and that the label or leaflets contained a false or misleading statement, then there will be a third question for you to determine; that is, whether the Vrilium Corporation, Erickson or Nelson, or any or all of them, were responsible for the shipment. If you find that the

devices with labeling containing a false or misleading statement were shipped from Chicago to Michigan and that the defendants or any or all of them were responsible therefor, then you should return a verdict of guilty against the defendant or those defendants you find responsible.

"The intent with which the defendants, or any of them, acted is not a question for your consideration in this case. The Government is not required to prove a wrongful intent or an awareness of wrongdoing. It is not necessary for you to find that the Vrilium Products Co., George C. Erickson, Robert T. Nelson, Jr., or any of them, intended to make false or misleading statements in the labeling. The question of whether the defendants or any of them acted in good faith is not material. It is sufficient for a finding of guilt that the statements complained of, in the labeling or any one of them, be proven to be false or misleading, beyond a reasonable doubt, regardless of whether the defendants, or any of them, were aware that any one of the statements was false or misleading. The persuasive effect of a false or misleading statement in labeling, on the reader's mind, is the same whether the representations were made in good faith or not. It is the responsibility of the person or persons who use the channels of interstate commerce for the distribution of devices to be assured that the labels and the labeling of the devices contain no false or misleading statement or representation. The statute places the burden of acting, at their own risk, upon persons who ship devices; it does not place the risk of the use of devices upon the public, who are largely helpless in this regard.

"The Federal Food, Drug, and Cosmetic Act makes 'any person' who violates the section involved in this case guilty of a 'misdemeanor.' It specifically defines 'person' to include a 'corporation.' But the only way in which a corporation can act is through the individuals who act on its behalf. The commission of a 'misdemeanor' makes all those who shared responsibility in the business process resulting in an unlawful interstate shipment and who have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, putting into the stream of interstate commerce misbranded devices, equally guilty.

"The fact than an information has been filed is not evidence; nor is the information evidence; and neither the information nor the return thereof should be considered by you in determining the guilt of the defendants, or any of them. The information is not to be treated by you as raising any kind of presumption or creating any kind of prejudice against these defendants, or any of them. The information is simply the form or manner prescribed by law for preferring a charge against an individual or corporation, and must be regarded in that light, and in no other light.

"This is a criminal case, and the law in such cases is that a defendant comes into court presumed to be innocent, and that presumption protects him until such time, if such time shall come, when the jury shall believe from the evidence in the case, beyond a reasonable doubt, that the defendant is guilty as charged in the information.

"The guilt of an accused is not to be inferred because the facts proven are consistent with his guilt, but, on the contrary, before there can be a verdict of guilty you must believe from all the evidence, and beyond a reasonable doubt, that the facts proven are inconsistent with innocence; if two conclusions can reasonably be drawn from the evidence, one of innocence and one of guilt, you should adopt the former.

"The defendants on trial have pleaded not guilty. This puts the burden of proving the charges in the information upon the Government, and you cannot find the defendants or any of them guilty unless, from all the evidence, you believe them or any of them guilty of the offenses charged in this information beyond a reasonable doubt.

"The Court instructs the jury in this case that the burden of proof never shifts to the defendants. They are presumed to be innocent and the burden of proof remains upon the Government throughout the case to prove that the claims or any one of them made by the defendants in their labeling are misleading and each is false.

"A reasonable doubt is what the term implies,—a doubt founded on reason. It does not mean every conceivable kind of doubt. It does not mean a doubt that may be purely imaginary or fanciful, or one that is merely captious or speculative; it means, simply, an honest doubt that appeals to reason and is

founded upon reason. If, after considering all the evidence in the case, you have such a doubt in your mind as would cause you, or any other reasonable prudent person, to pause or hesitate before acting in a grave transaction of your own life, then you have such a doubt as the law contemplates as a reasonable doubt.

"Two of the defendants have testified on the witness stand. You have heard their testimony. The fact that they are defendants does not mean that they cannot tell the truth. You should weigh the testimony of a defendant by the same rules that you weigh the testimony of any other witness. But you should keep in mind that they are defendants in the case, and, of course, have a vital interest in the outcome of the trial.

"The Federal Food, Drug, and Cosmetic Act defines 'labeling' to mean 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'

"You are instructed that the leaflets and carton labels, such as Government Exhibits 13E and D, involved in the shipment referred to in the information, constitute labeling within the meaning of the Act.

"The Federal Food, Drug, and Cosmetic Act provides that a device shall be deemed to be misbranded if its labeling is false or misleading in any particular.

"You are instructed that, as used in the Federal Food, Drug, and Cosmetic Act, the word 'false' applies to any representation or suggestion which is inaccurate, incorrect, untrue, or an erroneous statement of fact.

"You are instructed that the word 'misleading' as used in the Act applies to any written, printed, or graphic matter which misleads or deceives, or has a tendency to lead into error, to lead astray, or to lead into the wrong path. You are further instructed that deception may result from the use of statements not technically false or which may be literally true. The aim of the Act is as much to prevent deception which may result from indirection and ambiguity, as well as from statements or representations which are false. You are further instructed that it is not difficult to choose statements, representations, pictures, symbols, or slogans which will not deceive, and those which are ambiguous and liable to deceive should be read favorably to the accomplishment of the purpose of the Act, namely, the protection of the purchasing public and the public health. Statements that are ambiguous and liable to mislead, or which create or lead to false impressions in the mind of the reader, are misleading within the meaning of the law. In determining whether the labeling involved is false or misleading for any of the reasons claimed, you will consider whether the statements complained of are likely to create a false or misleading impression in the mind of any person who reads such statements pertaining to the claims made for the devices involved in this case.

"In determining whether any statement in the labeling, as previously explained to you, is false or misleading in any particular, and in determining whether any such statement represents or suggests that the article of device when used according to directions is effective in the cure, mitigation, treatment, or prevention of any condition, disease, or illness in general, you are instructed that the words, statements, or graphic material used in such labeling should be given their ordinary meaning, that is, the meaning that would be attributed to them by the ordinary person to whom they are addressed. you believe beyond a reasonable doubt from the creditable evidence that an ordinary person after reading any of the statements complained of in said labeling would ordinarily be led to believe that a particular condition, or illness in general, would be cured, mitigated, or prevented by the recommended use of the device, or that the device when so used would be a competent treatment for such a disease, or condition or illness in general, and if you further believe beyond a reasonable doubt from the credible evidence that the device when used as directed would either not cure, mitigate, or prevent, nor be a competent treatment for such condition, disease, or illness in general, then the device is misbranded and shipments thereof in interstate commerce constitute violations of the Federal Food, Drug, and Cosmetic Act.

"The term 'device' is defined in the Federal Food, Drug, and Cosmetic Act and as it applies to the issues in this case 'means instruments, apparatus, and contrivances, intended (1) for use in the diagnosis, cure, mitigation, treatment,

or prevention of disease in man'; or '(2) to affect the structure or any function of the body of man.'

"You are instructed that the devices referred to in the information filed herein are 'devices' within the meaning of the Federal Food, Drug, and Cosmetic Act.

"You are instructed that under the Federal Food, Drug, and Cosmetic Act the causing of the introduction or delivery for introduction into interstate

commerce of any device that is misbranded is unlawful.

3421-34401

"If you find that the labels or the leaflets of the devices involved in this information contain representations or suggestions that the devices when used as directed are effective in the cure, mitigation, treatment, or prevention of the diseases, disorders, conditions, or symptoms that are enumerated or for illness in general, or in affecting the structure or any function of the body of man, and, if you further find that the devices when employed in-accordance with the directions for use will not be effective in the cure, mitigation, treatment, or prevention of any of the diseases, disorders, conditions, or symptoms enumerated or illness in general, or in affecting the structure or any function of the body of man, you will then find that the devices are misbranded.

"You are instructed that the devices here involved were misbranded if you are satisfied that the Government has proved beyond a reasonable doubt from the evidence that any single statement made in the labeling of the devices regarding the effect of the devices when used according to directions in the cure, mitigation, treatment, or prevention of any of the diseases, disorders, conditions or symptoms enumerated in the information, or illness in general, or in affecting the structure or any function of the body of man, was either false or misleading. In this regard it is not necessary for you to find that every statement complained of by the Government is false or misleading, but if the Government has sustained its contention in regard to any one of them, then it would be your duty to render a verdict in its favor.

"The Government is not required to prove that the devices involved are dangerous to health or harmful in any way. Whether the use of the devices would be harmless is not for your consideration. Any testimony tending to show that the devices when used according to directions may delay proper treatment, resulting in permanent injury or death to the user is over and above what the Government is actually required to prove in order for you to find that the contexts of the labels or leaflets resulted in a misbranding of the devices. The Government is only required to prove the presence of one false or misleading

statement in the labels or leaflets.

"The labels and labeling of the devices received in evidence indicate compliance with trade mark and copyright laws. The fact that there has been compliance with the laws involving trade marks and copyrights does not give the defendants, Vrilium Products Co., George C. Erickson, or Robert T. Nelson, Jr., or any of them, the right to disseminate any false or misleading statement on the labels or in the labeling of these devices. In reaching your verdict you will completely disregard all references on the labels and in the labeling to

patents, trade marks and copyrights.

"You are the sole judges of the credibility and the weight which is to be given to the testimony of the witnesses who have taken the stand during this trial. You are the sole judges of the facts. You must, however, accept the law as given to you by the Court. In weighing the testimony of the various witnesses, you should take into consideration their interest, if any, in the outcome of the trial; their demeanor on the stand; their intelligence, training, experience, learning, and knowledge, or lack of any of them; their means and opportunities of seeing, knowing, and remembering the things testified to by them; whether they are corroborated or contradicted by other credible witnesses, and the facts in evidence; whether the things testified to by them are reasonable or unreasonable, and all other facts and circumstances in evidence. You may take into consideration their bias or prejudice, their interest, financial, or otherwise, which any witness may have in the outcome of the case, and weigh that testimony in accordance with all of the considerations which I have given you.

"Lay persons may properly testify to symptoms such as pains, aches, itching, stiffness or fatigue which they personally experience or conditions such as swelling, discoloration, cuts, abrasions of the skin, which they are able to see. They may testify to the taking of medication or other types of treatment taken

in connection with whatever they may be suffering from or afflicted with. They may properly testify to any alterations of those symptoms or conditions subsequent to resort to the medication or treatment. Any testimony or suggestions by such lay persons that improvement or aggravation of such symptoms or conditions was brought about by the use of any particular medication or treatment should be disregarded by you since such persons are not competent or qualified to determine the cause of benefit or improvement in physical condition.

Certain testimony in this case has been objected to and sustained. Certain testimony has been stricken. You are to disregard testimony that has You are also to disregard that testimony of any lay witness been stricken. in which that person stated that he or she was suffering from any particular disease or that he or she was being treated for any particular disease. A lay person is not competent so to testify. Anything that a doctor told a lay person is hearsay. The doctor is the only qualified person to testify concerning the disease present and the reasons for the resort to treatment prescribed. Although a lay person is competent to testify to a change in recognizable symptoms, a doctor is the only qualified person to testify as to whether or not a cure has been effected, or any particular type of medication or treatment was effective in bringing about a cure or an alleviation of the ailment. proneness of lay persons to err in accrediting responsibility for benefits to health is well understood. The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little.

"Ordinarily in the trial of cases witnesses are confined in their testimony to facts within their personal knowledge. They are not permitted to draw conclusions or express opinions. There is an exception to that rule, however, which is this: That when the points in issue are concerned with a particular subject matter with respect to which there are trained persons who have had special education, training and experience in particular fields, such persons are known as 'experts' and because of their special education, training and experience are permitted to express opinions.

"You are required, of course, to weigh and evaluate the testimony of an expert witness precisely as you weigh and evaluate the testimony of any non-expert witness. That is, you will consider the probability and reasonableness of the things to which the 'expert' has testified, his interest in the outcome of the case, his education, training and experience, his standing in the profession, or lack of it, and the breadth of his experience in the subject matter which would enable him to arrive at a correct conclusion. In this regard you should ask yourself: Is this witness, as a matter of fact, an expert qualified by scientific education, training and experience to acquaint me with the scientific facts?

"Certain of the evidence in this case has consisted in the testimony of physicians and scientists, including chemists and nuclear physicists. Some physicians testified to their personal observations of the results or lack of results of the use of vrilium tubes on human patients. Physicists testified to the results they obtained in testing the tubes by means of scientific instruments. Chemists testified to their analyses of the powder-like material contained in the glass capsules. Facts established by recognized scientific investigations conducted by fair-minded, well-qualified scientific experts are deserving of considerable weight. You may attach greater weight to the testimony of such persons pertaining to scientific investigations than to the testimony of lay persons.

"If you believe from the evidence that any witness in this case has knowingly and wilfully testified falsely on this trial to any matter material to the issues in this case, you are at liberty to disregard the entire testimony of such witness, except in so far as it has been corroborated, if you find it has been corroborated, by other credible evidence, or by facts and circumstances proven on the trial.

"During a trial it often becomes the duty of counsel for the parties to object to questions, or to evidence, and I instruct you that you shall not take into consideration against such party either such objections or the number of them, nor permit yourselves to be in any way influenced by such objections against the parties.

"You should not allow sympathy for any of the defendants to this action or prejudice against any to influence your deliberations. You should not be influenced by anything other than the law, as I have explained it to you, and the evidence in the case. During the course of this trial articles have appeared in local newspapers pertaining to this trial, which you may or may not have read. You must completely disregard anything you may have read in newspapers or in any other type of publication about this case. You must also disregard anything you may have heard from persons other than witnesses who have appeared before you in this court room.

"I must instruct you that the question of the possible punishment of the defendants, or any of them, in the event of a conviction is not a matter for the jury to consider and should not, in any way, enter into your deliberations. The law imposes the duty of fixing a penalty solely upon the Court, who tries to perform it fairly and with due consideration for all the circumstances. The function of the jury is to weigh all the evidence and determine the guilt or innocence of the defendants, or any of them, solely from that evidence.

"You will be given a number of forms of verdict, and if your finding is the same as to all the defendants, you will use the same form, naming all of the

defendants which expresses your vote.

"If your finding is not the same as to all of the defendants, then you will use the form naming the defendants individually which expresses your verdict

as to each defendant.

"In signing the verdict the foreman signs the top line and the remaining jurors will sign the remaining lines. The women members of the jury or the lady members who are married will sign their own names, not your husband's. Your first duty upon retiring will be to elect a foreman before you proceed with your deliberations."

(Whereupon the jury retired to consider the verdict.)

A verdict finding the defendants guilty was returned by the jury on April 5, 1950. On April 26, 1950, after the denial of the defendants' motion for a new trial, the court imposed the fines and sentences as indicated in the court opinion set forth below. The case was appealed to the United States Court of Appeals for the Seventh Circuit; and on November 13, 1950, the following opinion was handed down by that court:

FINNEGAN, Circuit Judge: "Defendants-appellants seek to reverse a conviction, based upon the verdict of a jury finding them guilty of a violation of the

Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 301-392).

"The information charging the offense was filed on January 20, 1947. It contained only one count. It charged that the defendants, on or about June 25, 1945, did unlawfully cause to be introduced and delivered for introduction into interstate commerce, for delivery to one Dr. R. C. Kistler, at Wyandotte, Michigan, one carton containing a number of tubes known as 'Vrilium Catalytic Barium Chloride,' a device within the meaning of 21 U. S. C. A. 321 (h), that said device when so caused to be introduced and delivered in interstate commerce was, then and there, misbranded within the meaning of U. S. C. A. 352 (a).

"On April 12, 1948, the defendants-appellants were arraigned and pleaded not guilty. At that time they were represented by counsel, and the case was set for trial on October 6, 1948. After several continuances, the case was set down for April 4, 1949. On March 25, 1949, the first attorney they had employed withdrew. On April 4, 1949, Justus Chancellor and his son Justus.

Jr., were substituted as counsel for defendants-appellants.

"The defendants consented to the substitution. Mr. Chancellor, Sr., appeared on the motion to substitute. He then requested a continuance for sixty days, but this was denied and this case was re-set for April 11, 1949.

"On April 8, 1949, the elder Mr. Chancellor again appeared on behalf of

"On April 8, 1949, the elder Mr. Chancellor again appeared on behalf of the defendants and moved for additional time to prepare for trial. The court then set the matter for trial on April 18, 1949. Thereafter the case was continued from time to time. Some continuations were on motion of the Government, and others were made to suit the convenience of the court. The younger Mr. Chancellor never appeared in the trial court on behalf of the defendants-appellants, although motions to quash the complaint and dismiss the information were filed and argued by his father.

"Finally, and nearly a year later, on March 20, 1950, the case was called for trial. At that time Mr. Chancellor, Sr., requested a continuance because his son, who, he then said, was to try the case, had suffered a heart attack on the previous day and would be unable to proceed for two weeks. The father then claimed that because of his age he had not assumed the burden of a trial for several years. He also said that his hearing was not 'extra good.'

"The court denied the continuance and the trial began. The Government took five whole days to present its case. The defense consumed seven days in the presentation of its evidence. An additional day was expended in arguments and instructions to the jury, and to its deliberation to reach a verdict.

"On April 5, 1950, the jury returned its verdict finding the defendants

"On April 26, 1950, the defendants, accompanied by Mr. Chancellor, Sr., again appeared before the trial court. A motion for a new trial was filed and

denied, and sentence was pronounced.

"The individual defendants, George C. Erickson and Robert T. Nelson, Jr., were sentenced to the custody of the Attorney General for one year and fined \$1,000 each; the corporate defendant, Vrilium Products Company, was fined \$1,000. On the same day, Mr. Chancellor, Sr., filed notice of appeal on behalf of defendants-appellants.

"At a later date, May 10, 1950, the attorneys who now appear in this court

were substituted as attorneys for the appellants.

"It is here argued that the convictions should be reversed because:

1. The appellants were deprived of their Constitutional right to effective counsel of their own choice, which rendered the judgment of conviction against them a nullity;

2. The prosecution failed to prove that the defendants had shipped the

devices in question in interstate commerce, and

3. That one instruction given was contrary to the evidence, usurped

the function of the jury and constituted reversible error.

"The first contention involves an attack on the denial by the trial court of defendants' motion for continuance made on March 20, 1950.

"The ground upon which their request for delay was based was that Mr. Chancellor, Jr., had been stricken by a heart attack on the previous day. He was a member of the law firm, whose appearance had been filed on behalf of and with the consent of the defendants. Although he was one of their attorneys of record for more than eleven months, he never at any time appeared on their behalf. He did not even appear with his father and co-partner when the motion to quash the information and dismiss the case was argued. The father, although an elderly gentleman, had carried the entire burden up to that time; the son's name had never been even mentioned.

"Under such circumstances the law is plain—the rule to be applied was well expressed in Isaacs v. United States, 159 U. S. 487, a prosecution for murder

in the Territory of Alaska, where it was said on page 489:

That the action of the trial court upon an application for a continuance is purely a matter of discretion, and not subject to review by this court, unless it be clearly shown that such discretion has been abused, is settled by too many authorities to be now open to question.

"The same rule was followed in Hardy v. United States, 186 U. S. 224. The reason for which continuance was requested in both those cases was the absence of material witnesses.

"In Lias, et al., v. United States, 51 F. 2d 215, in speaking of assignments of error, in a prosecution for conspiracy to violate the Prohibition Law, the court said on page 216, et seq.:

the first of which is that the court erred in not granting a continuance or a change of venue, on the ground of the illness of the leading counsel for the defendant, who was the head of the firm representing them, and because of articles appearing in various newspapers dealing with the case and an alleged attempt to kill one of the prosecution's witnesses in the case.

The question of continuance was one addressed to the sound discretion of the trial court. This has been repeatedly held by this court, and it is scarcely necessary to cite authorities to that effect.

Here defendants were represented by two other members of the law firm, of which the leading member was ill; one of the attorneys representing appellants at the trial having been present before the commissioner. There was no good reason for continuance of the case upon ground of the illness of one of several attorneys, and the motion was properly denied. * * *

"On certiorari granted, the Supreme Court affirmed the Lias case in a per

curiam opinion, 284 U.S. 584.

"In the case at bar, appellants were represented by counsel of their own choice. We have examined the record and can find no indication that their counsel was incompetent or negligent. The insinuations now made on behalf of appellants that he was "ineffective" because of the loss of his sense of hearing, finds no justification in this record. In the face of the facts and circumstances shown by this record the first contention of the appellants

must be over-ruled.

"The contention that the Government failed to show beyond a reasonable doubt that the devices and labels in question were shipped in interstate commerce is likewise untenable. The appellants themselves called many witnesses from neighboring states to show that they had used devices similar to those in question with beneficial results. Many of these witnesses actually dealt in such devices. On this record it might fairly be said that there is some conflict in the testimony that the devices were falsely labeled. There can be no question that the devices, or others like them, were introduced into interstate commerce. The shipment charged in the information was adequately proven by the testimony of the agent for the Railway Express Agency and its record, as well as consignee who appears to have been an agent for the defendant company engaged in part, at least, in selling their tubes.

"As far as the third contention is concerned, it is important to note that the appellants have taken from the instructions of the court to the jury, transcript of which covered more than fifteen pages, four lines, and sought to make it appear therefrom that the court intended to direct the jury that the leaflets and labels therein referred to had actually been shipped in interstate commerce. This is decidedly unfair and improper as will become evident when the whole charge is considered.

"At the outset of his instructions, the court said:

There are two broad general questions involved in the case with which you will be required to concern yourselves. The first pertains to the interstate commerce phase. In that regard the Government has charged the device accompanied by a label and leaflet were shipped in interstate commerce from Chicago to Wyandotte, Michigan. You will have to decide whether the device and labeling were so shipped. If you find that the device and labeling were not shipped from Chicago to Wyandotte then it will be necessary for you to return a verdict of not guilty for all the defendants. If you decide the device and labeling were shipped from Chicago to Michigan, for your second consideration it will then be necessary for you to determine whether or not the labels and leaflets contain a false and misleading statement.

"Our examination of the record convinces us that the jury was fully and fairly instructed by the trial court, and that its verdict finding the defendants guilty is amply supported by the evidence.

"The judgment of the District Court is affirmed."

On November 27, 1950, a petition for rehearing was filed by the defendants with the United States Court of Appeals for the Seventh Circuit, and was denied on December 15, 1950. The defendants thereupon filed a petition for certiorari with the United States Supreme Court, and this petition was denied on March 12, 1951.

3437. Misbranding of Hollywood Vita-Rol device. U. S. v. 125 Cartons * * *. (F. D. C. No. 30382. Sample No. 24951-L.)

LIBEL FILED: January 15, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 4 and 6, 1950, by the S & D Engineering Co., from Glendale, Calif.

PRODUCT: 125 cartons each containing 1 Hollywood Vita-Rol device at Philadelphia, Pa., in possession of Gimbel Bros. A leaflet entitled "Hollywood Vita-Rol Instructions" was shipped with the product. The device consisted of an electrically heated roller covered with corrugated rubber.

RESULTS OF INVESTIGATION: There was on display in the consignee's store, together with the device, a placard entitled "Vita-Rol" which had been prepared by Gimbel Bros.

Nature of Charge: Misbranding, Section 502 (a), the statement appearing in the above-mentioned leaflet, namely, "Both men and women use the Vita-Rol to maintain a slim, trim, figure by massaging those troublesome bulges or spots," was false and misleading. The statement represented and suggested that the device was effective for spot reducing, whereas the device was not effective for such purpose. The device was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the statement appearing in the abovementioned placard, namely, "roll away pounds," was false and misleading. The statement represented and suggested that the device was effective for reducing, whereas the device was not effective for such purpose. The device was misbranded in the latter respect while held for sale after shipment in interstate commerce.

DISPOSITION: May 9, 1951. Gimbel Bros., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be released under bond for relabeling and that the leaflets and placards be destroyed, under the supervision of the Food and Drug Administration.

3438. Misbranding of Spectro-Chrome device. U. S. v. 1 Device * * *. (F. D. C. No. 16846. Sample No. 16303–H.)

LIBEL FILED: July 16, 1945, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about June 6, 1945, by the Dinshah Spectro-Chrome Institute, from Newfield, N. J.

Product: 1 Spectro-Chrome device at Milwaukee, Wis. The construction and appearance of the device was essentially the same as that of the device involved in notices of judgment on drugs and devices, No. 2098. The device was accompanied by various pieces of printed and graphic matter.

NATURE of CHARGE: Misbranding, Section 502 (a), the labeling of the device contained false and misleading curative and therapeutic claims in substantially the same respect as that of the device involved in notices of judgment on drugs and devices, No. 2098.

DISPOSITION: On November 26, 1945, no claimant having appeared, the court ordered that the device be released to the Food and Drug Administration for the purpose of testing. On October 7, 1946, the court entered an order authorizing the Government to retain possession of the device and its accompanying labeling until the further order of the court. On May 29, 1951, the court entered an order authorizing the Food and Drug Administration to retain possession of the device and the accompanying labeling and to make such use of the device and labeling as it may desire.

DRUG FOR VETERINARY USE*

3439. Misbranding of Master Liquid Hog Medicine. U. S. v. 7 Cans, etc. Tried to the court; verdict for the Government. Decree of condemnation and destruction. Case appealed to U. S. Court of Appeals for Eighth Circuit; appeal subsequently dismissed. (F. D. C. No. 26934. Sample No. 25585-K.)

LIBEL FILED: March 18, 1949, Northern District of Iowa.

ALLEGED SHIPMENT: On or about January 7, 1949, by Master Laboratories, from Omaha, Nebr.

PRODUCT: 7 3-gallon cans and 3 5-gallon cans of Master Liquid Hog Medicine at Steamboat Rock, Iowa, together with a number of leaflets entitled "Master Treatment for Brood Sows."

Analysis showed that the product consisted essentially of an aqueous solution of sodium thiosulfate, sodium hydroxide, sodium carbonate, potassium arsenite, with phenolic compounds such as cresote, guaiacol, and betanaphthol, nicotinic acid, and anise oil.

Nature of Charge: Misbranding, Section 502 (a), certain statements on the can labels and in the leaflets were false and misleading. These statements represented and suggested that the article was effective in the prevention and treatment of scouring pigs, and in the treatment of pigs which are scouring from the disease known as necro, whereas the article was not effective for such purposes.

Disposition: Master Laboratories appeared as claimant and filed an answer denying that the article was misbranded. The case came on for trial before the court on May 9, 1950, and continued through May 11, 1950. On May 20, 1950, the court handed down its findings of fact and conclusions of law to the effect that the article was misbranded; and, on the same day, the court entered a decree providing for the condemnation of the product and its destruction.

A notice of appeal to the U. S. Court of Appeals for the Eighth Circuit was filed by the claimant on July 17, 1950. Thereafter, several continuances were granted by the appellate court, upon claimant's motion extending the time to print, serve, and file copies of the record and brief of the claimant. Following the filing of claimant's printed record and printed brief, a motion to strike such record and brief and to dismiss the appeal was filed by the Government. On May 2, 1951, the U. S. Court of Appeals for the Eighth Circuit handed down the following decision:

"This cause came on to be heard on the motion of appellee, presented by Mr. William B. Danforth, Assistant United States Attorney, to strike appellant's printed record and printed brief, and to dismiss the appeal from the United States District Court for the Northern District of Iowa, at appellant's costs. Appellant's resistance to the motion is submitted to the Court without oral argument.

"It is apparent that the printed record on appeal has been prepared in utter disregard of the provisions of the Rules of this Court, and the evidence has been reduced to such extent that this Court cannot possibly determine therefrom the questions presented for decision. For failure of appellant to print and file an adequate record containing in narrative form so much of the entire record as is essential to the appeal, It is, after due consideration, now here Ordered and Adjudged by this Court that the appeal in this cause be, and the same is hereby, dismissed at the costs of the appellant."

^{*}See also No. 3429.

Subsequent to the decision of the circuit court of appeals dismissing the appeal, a motion for rehearing was filed by the claimant but was denied on May 9, 1951.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

3440. Misbranding of injectable liver. U.S. v. 44 Vials * * *. (F. D. C. No. No. 30400. Sample No. 25131-L.)

LIBEL FILED: January 25, 1951, Eastern District of Pennsylvanià.

Alleged Shipment: On or about December 15, 1950, by the American Bio-Chemical Corp., from Los Angeles, Calif.

Product: 44 unlabeled vials of injectable liver at Philadelphia, Pa. The product was received by the consignee in two packages, each of which contained 25 unlabeled vials with a label on the outer wrapper reading, in part, "30 cc Vial * * * Injectable Liver Each cc contains the soluble extractives derived from 100 grains of fresh beef liver. * * * For Intramuscular Use."

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (g), the article purported to be liver injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the article was not labeled as prescribed in the compendium since its label failed to show any potency assigned to it by the U. S. P. Anti-anemia Preparations Advisory Board.

DISPOSITION: May 14, 1951. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3421 TO 3440

PRODUCTS

N. J. No.	N. J. No.
Amphetamine sulfate tablets 3422	Hormotone "T" tablets 3421
Androgenic substances 3421, 3422	Injectable liver 3440
Biotropin 3432	Jalap root 3431
Brown's powdered goat milk 3434	Liver, injectable 3440
Burdock root 3431	Master Liquid Hog Medicine 23439
Clinical thermometers 3433	Metandren Linguets 3421
Cocillana bark 3431	Methyltestosterone tablets 3421, 3422
Combisul tablets 3424, 3426	Mineral solution 3429
Desoxyn Hydrochloride tab-	Neo-Hombreol tablets 3421
lets 3424, 3425	Oreton-M tablets 3421
Devices 3433, 3436-3438	Phenobarbital tablets 3423
Dexedrine Sulfate tablets 3422-3424	Phenothiazine drench 3430
Estinyl tablets 3421	Premarin tablets 3427
Estrogenic substances 3421, 3427	Sal-Trag Compound 3428
Goat milk, powdered 3434	Spectro-Chrome device 3438
Hollywood Vita-Rol device 3437	Squill, white 3431

^{1 (3436)} Prosecution contested. Contains instructions to the jury and opinion of the court.

² (3429) Seizure contested.

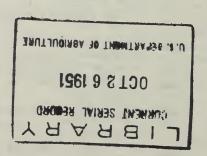
3421-3440] NOTIC	ES OF	JUDUMENT
N	. J. No.	N. J. No.
Sulfadiazine tablets		Veterinary preparations 3429,
Sulfathiazole tablets		3430,2 3439
Tates Antiseptic Germicide		Vita-Rol device, Hollywood 3437
Thermometers, clinical		Vrilium Catalytic Barium Chlo-
Thyroid tablets	3425	ride tube 13436
Inyrold tablets	0120	White squill 3431
		, mice equipment of the control of t
SHIPPERS MANIII	FACTUR	ERS, AND DISTRIBUTORS
,		
	. J. No.	N. J. No.
Ace Mail Order Co.:		Garner, R. G., Jr.:
Estinyl tablets, Hormotone "T"		Combisul tablets, Dexedrine
tablets, Oreton-M tablets,		Sulfate tablets, and Desoxyn Hydrochloride tablets 3424
Neo-Hombreol tablets, and	0.404	
Metandren Linguets	3421	Garner Pharmacy. See Garner,
American Bio-Chemical Corp.:		R. G., Jr.
injectable liver	3440	Gill, F. R.:
Atomic Basic Chemicals Corp.:		Combisul tablets, Dexedrine
phenothiazine drench	3430	Sulfate tablets, and Desoxyn
Bernstein, Mendel:		Hydrochloride tablets 3424
Estinyl tablets, Hormotone "T"		Gimbel Bros.:
tablets, Oreton-M tablets,		Hollywood Vita-Rol Device 3437
Neo-Hombreol tablets, and		Green, Carl and Jesse:
Metandren Lingeuts	3421	
Brant Building Pharmacy Co.:		Hartman, Robert: Combisul tablets, Dexedrine
methyltestosterone tablets,		Sulfate tablets, and Desoxyn
Dexedrine Sulfate tablets,		Hydrochloride tablets 3424
and amphetamine sulfate		Ideal Thermometer Co., Inc.:
tablets	3422	clinical thermometers 3433
Brown, A. G., and Mrs. D. T.:		Lederman, Sol:
Brown's powdered goat milk	3434	Premarin tablets 3427
Carnrick, G. W., Co.:	0101	Lippmann, Max:
Hormotone "T" tablets	3421	Premarin tablets 3427
Ciba Pharmaceutical Products.	9121	Master Laboratories:
Inc.:		Master Liquid Hog Medicine2 3439
Metandren Linguets	9491	Nelson, R. T., Jr.:
	0441	Vrilium Catalytic Barium Chlo-
Crow, H. J.:	ا سانه شدر	ride tube13436
phenobarbital tablets and Dex		0 . *
edrine Sulfate tablets		Neo-Hombreol tablets 3421
Dinshah Spectro-Chrome Insti-		Physicians Pharmacy See Brant
tute:	0.10.	OC Building Pharmacy Co
Spectro-Chrome device	3438	Poulston, H. D.:
Eason, Thomas:		
mineral solution	3429	sulfathiazole tablets and Com- bisul tablets 3426
Erickson, G. C.:	-	Poulston Drug Co.
Vrilium Catalytic Barium Chlo-	- The second	sulfathiazole fablets and Com-
ride tube	¹ 3436	bisul tablets 3426

 $^{^{1}\}left(3436\right)$ Prosecution contested. Contains instructions to the jury and opinion of the court.

² (3439) Seizure contested.

N. J. No	N. J. No.
Prentiss, R. J., & Co., Inc.:	Southern Minerals, Inc.:
burdock root, cocillana bark,	mineral solution 3429
jalap root, and white squill 3431	Talbert, B. F.:
Research Laboratories, Inc.:	phenobarbital tablets and Dexe-
Sal-Trag Compound 3428	drine Sulfate tablets 3423
Robertson, J. K.:	Tate Chemical Co., Inc.:
phenobarital tablets and Dexe-	Tates Antiseptic Germicide 3435
drine Sulfate tablets 3423	Thompson-Hayward Chemical Co.:
Roche-Organon, Inc. See Orga-	phenothiazine drench 3430
non, Inc.	Vogler, Edward:
S & D Engineering Co.:	methyltestosterone tablets, Dex-
Hollywood Vita-Rol device 3437	edrine Sulfate tablets, and
Schering Corp.:	amphetamine sulfate tablets_ 3422
Estinyl tablets and Oreton-M	Vrilium Products Co.:
tablets 3421	Vrilium Catalytic Barium Chlo-
Schlonsky, T. J.:	ride tube13436
sulfadiazine tablets, Desoxyn	Weiner, Louis:
Hydrochloride tablets, and	methyltestosterone tablets, Dex-
thyroid tablets 3425	edrine Sulfate tablets, and
Sloan Drug Co.:	amphetamine sulfate tablets_ 3422
sulfadiazine tablets, Desoxyn	Wolman, Harry:
Hydrochloride tablets, and	sulfadiazine tablets, Desoxyn
thyroid tablets 3425	Hydrochloride tablets, and
Smith's, Inc.:	thyroid tablets 3425
phenobarbital tablets and Dexe-	
drine Sulfate tablets 3423	

 $^{^{1}\}left(3436\right)$ Prosecution contested. Contains instructions to the jury and opinion of the court.



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3441-3460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

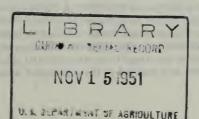
CHARLES W. CRAWFORD, Commissioner of Food and Drugs.

WASHINGTON, D. C.

CONTENTS *

Page	Page
Drugs actionable because of failure	Drugs and devices actionable be-
to bear adequate directions or	cause of false and misleading
warning statements 434	claims 443
Drugs actionable because of devia-	Drugs for human use 443
tion from official or own stand-	Drugs for veterinary use 451
ards440	Index451

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3442-3448; omission of, or unsatisfactory, ingredients statements, Nos. 3445-3447, 3450; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3441-3448; 3450; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3441-3448.



967728-51-1

433

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3441. Misbranding of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets. U. S. v. The Eckerd Drug & Notion Co., Edmond R. Anderson, Sr., and Charles F. Potts. Pleas of guilty. Fine of \$100 against company suspended; fine of \$100, plus costs, against each individual. (F. D. C. No. 30040. Sample Nos. 52070-K, 52098-K, 72183-K, 72220-K, 72415-K.)
- INFORMATION FILED: March 5, 1951, Northern District of Ohio, against the Eckerd Drug & Notion Co., a corporation, Akron, Ohio, and against Edmond R. Anderson, Sr., secretary and general manager of the corporation, and Charles F. Potts, a pharmacist for the corporation.
- INTERSTATE SHIPMENT: Fom the State of Pennsylvania into the State of Ohio, of quantities of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets.
- ALLEGED VIOLATION: On or about October 28 and December 29, 1949, and January 13 and February 16 and 20, 1950, while the drugs were being held for sale at the Eckerd Drug & Notion Co., after shipment in interstate commerce, various quantities of the tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

The Eckerd Drug & Notion Co. was charged with causing the acts of repacking and sale of the drugs involved in each of the five counts of the information; and, in addition, Edmond R. Anderson, Sr., in two of the counts, and Charles F. Potts, in one of the counts of the information, were charged with causing such acts to be done in connection with the drugs involved in those counts.

- Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use. Further misbranding, Sections 502 (b) (1) and (2), a portion of the repackaged Benzedrine Sulfate tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and various portions of the repackaged Benzedrine Sulfate tablets and the Dexedrine Sulfate tablets failed to bear labels containing statements of the quantity of the contents.
- DISPOSITION: March 30, 1951. Pleas of guilty having been entered, the court imposed a fine of \$100 against the company, which fine was suspended by reason of insolvency. The court also imposed a fine of \$100, plus costs, against each individual.
- 3442. Misbranding of thyroid tablets, Dexedrine Sulfate tablets, phenobarbital tablets, and Amytal tablets. U. S. v. Arthur C. Moreland. Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30024. Sample Nos. 61897-K, 61898-K, 77120-K, 77703-K, 77704-K, 77716-K.)
- INFORMATION FILED: January 31, 1951, Western District of Arkansas, against Arthur C. Moreland, Ashdown, Ark.
- Interstate Shipment: From the States of Missouri, Pennsylvania, and Indiana, into the State of Arkansas, of quantities of thyroid tablets, Dexedrine Sulfate tablets, Benzedrine Sulfate tablets, phenobarbital tablets, and Amytal tablets.
- ALLEGED VIOLATION: On or about March 7, 9, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged Dexedrine Sulfate tablets, Benzedrine Sulfate tablets, phenobarbital tablets, and Amytal tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *phenobarbital tablets* and the *Amytal tablets* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: May 30, 1951. A plea of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendant on probation without supervision for 1 year.

3443. Misbranding of thyroid tablets, diethylstilbestrol tablets, Dexedrine Sulfate tablets, and phenobarbital tablets. U. S. v. Willie D. Phillips (Phillips Bros. Drug Co.). Plea of nolo contendere. Sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30018. Sample Nos. 61895-K, 76415-K, 77701-K, 77711-K.)

Information Filed: January 31, 1951, Western District of Arkansas, against Willie D. Phillips, trading as the Phillips Bros. Drug Co., Ashdown, Ark.

INTERSTATE SHIPMENT: From the States of Missouri, New York, and Pennsylvania, into the State of Arkansas, of quantities of thyroid tablets, diethylstilbestrol tablets, Dexedrine Sulfate tablets, and phenobarbital tablets.

ALLEGED VIOLATION: On or about March 7, 9, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Dexedrine Sulfate tablets* and *phenobarbital tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged diethylstilbestrol tablets failed to bear labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- DISPOSITION: May 30, 1951. A plea of nolo contendere having been entered, the court suspended sentence against the defendant and placed him on probation for 1 year without supervision.
- 3444. Misbranding of thyroid tablets and phenobarbital tablets. U. S. v. Hugh
 Latimer (Latimer Drug Co.). Plea of nolo contendere. Sentence suspended and defendant placed on probation for 1 year. (F. D. C. No.
 30023. Sample Nos. 61893-K, 61900-K, 76414-K, 77118-K, 77712-K.)
- INFORMATION FILED: February 26, 1951, Western District of Arkansas, against Hugh Latimer, trading as the Latimer Drug Co., Lockesburg, Ark.
- INTERSTATE SHIPMENT: From the State of Indiana into the State of Arkansas, of quantities of thyroid tablets and phenobarbital tablets.
- ALLEGED VIOLATION: On or about March 7, 9, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

- *Disposition: May 30, 1951. A plea of nolo contendere having been entered, the court suspended sentence against the defendant and placed him on probation for 1 year without supervision.
- 3445. Misbranding of thyroid tablets, pentobarbital sodium capsules, and Tricombisul tablets. U. S. v. Harvey L. Claybaugh. Plea of nolo contendere. Fine of \$1,000 and sentence of 1 year in jail; jail sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 29998. Sample Nos. 71094–K, 71106–K, 71110–K, 71117–K.)
- Information Filed: February 21, 1951, District of Nevada, against Harvey L. Claybaugh, Las Vegas, Nev.
- INTERSTATE SHIPMENT: From the State of California into the State of Nevada, of quantities of thyroid tablets, pentobarbital sodium capsules, and Tricombisul tablets.
- ALLEGED VIOLATION: On or about January 30 and February 3, 4, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed

to bear adequate directions for use in that the labeling bore no directions for use.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the repackaged *Tricombisul tablets* failed to bear the common or usual name of each active ingredient of the drug, namely, sulfacetimide, sulfadiazine, and sulfamerazine; and, Section 502 (f) (2), the repackaged *thyroid tablets* and *Tricombisul tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: March 8, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$1,000 and a sentence of 1 year in jail. The jail sentence was suspended, and the defendant was placed on probation for 1 year.

3446. Misbranding of Desoxyn Hydrochloride tablets and pentobarbital sodium capsules. U. S. v. Charleston Drug Co. and Frank C. Harp. Pleas of nolo contendere. Fine of \$2,500 against individual; no sentence imposed against company. (F. D. C. No. 30010. Sample Nos. 71103-K, 71118-K, 71112-K, 71114-K, 71115-K.)

INFORMATION FILED: February 2, 1951, District of Nevada, against the Charleston Drug Co., a partnership, Las Vegas, Nev., and Frank C. Harp, a partner in the partnership.

INTERSTATE SHIPMENT: From the State of California into the State of Nevada, of quantities of Desoxyn Hydrochloride tablets and pentobarbital sodium capsules.

ALLEGED VIOLATION: On or about February 2, 3, 4, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and the place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged Desoxyn Hydrochloride tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged Desoxyn Hydrochloride tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

- Disposition: March 8, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,500 against the individual; no sentence was imposed against the company.
- 3447. Misbranding of Desoxyn Hydrochloride tablets, Triazoline tablets, and pentobarbital sodium capsules. U. S. v. Fisher Drug Co. and Harold C. Jenkins. Pleas of nolo contendere. Individual fined \$2,500 and sentenced to 1 year in jail; jail sentence suspended and individual placed on probation. No sentence imposed against company. (F. D. C. No. 30031. Sample Nos. 71096-K, 71104-K, 71107-K, 71109-K, 71116-K.)
- INFORMATION FILED: February 21, 1951, District of Nevada, against the Fisher Drug Co., a partnership, Las Vegas, Nev., and Harold C. Jenkins, a partner in the partnership.
- INTERSTATE SHIPMENT: From the State of California into the State of Nevada, of quantities of Desoxyn Hydrochloride tablets, Triazoline tablets, and pentobarbital sodium capsules.
- ALLEGED VIOLATION: On or about January 31 and February 2, 3, 4, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One every three hours as necessary," borne on the labeling of the *Triazoline tablets*, were not adequate directions for use and since the other repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the pentobarbital sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged Desoxyn Hydrochloride tablets failed to bear a label containing the common or usual name of the drug, namely, Desoxyn; Section 502 (e) (2), the repackaged Triazoline tablets failed to bear a label containing the common or usual name of each active ingredient, namely, sulfadiazine, sulfamerazine, and sulfathiazole; and, Section 502 (f) (2), the repackaged Desoxyn Hydrochloride tablets and Triazoline tablets failed to bear labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: March 8, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,500 and a sentence of 1 year in jail against the individual. The jail sentence was suspended, and the individual was placed on probation for 1 year. No sentence was imposed against the partnership.

3448. Misbranding of pentobarbital sodium capsules. U. S. v. Weaverton L. Fadely (Fadely's Drug Store No. 1) and D. Murray Hayden. Pleas of guilty. Fine of \$500 against Defendant Fadely and \$250 against Defendant Hayden. (F. D. C. No. 30047. Sample Nos. 53787-K, 53857-K.)

LIBEL FILED: April 18, 1951, Northern District of Alabama, against Weaverton L. Fadely, trading as Fadely's Drug Store No. 1, Birmingham, Ala., and D. Murray Hayden, pharmacist.

INTERSTATE SHIPMENT: From the States of New Jersey and Illinois into the State of Alabama, of quantities of pentobarbital sodium capsules.

ALLEGED VIOLATION: On or about October 5 and November 1, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repacked and sold without a prescription, which acts resulted in the repackaged drug being misbranded. Weaverton L. Fadely, as owner of the store was charged in both counts of the information, and D. Murray Hayden was joined as a defendant in count 2 and charged with the sale involved in that count.

NATURE of CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use,

DISPOSITION: May 4, 1951. Pleas of guilty having been entered, the court imposed a fine of \$500 against Defendant Fadely and \$250 against Defendant Hayden.

3449. Misbranding of Eden Creme. U. S. v. 1,601 Jars * * * (F. D. C. No. 29066. Sample No. 58673-K.)

LIBEL FILED: April 17, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about January 26, 1950, by Captivante Labs., Inc., from New York, N. Y.

PRODUCT: 1,601 jars of *Eden Creme* at Venice, Calif. Examination showed that the product was a soft cream containing approximately the declared amount of estrogenic hormones.

LABEL, IN PART: "Eden Creme * * * Approximately 30,000 International Units of Estrogens (substantially Estrones with traces of Equilin, Hippulin, Estradiol and Equilinin) in this jar. This jar should last during a 30-day consecutive period. Net contents not less than 2 ozs. Distributors House of Eden, 6411 Hollywood Blvd. Hollywood 28, Calif."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling did not specify any condition for which the article was to be used and did not state the structure or function of the body that the article was intended to affect.

DISPOSITION: May 21, 1951. The House of Eden, claimant, having filed an answer denying that the product was a drug and that it was misbranded as alleged in the libel, but subsequently having withdrawn its claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

3450. Adulteration and misbranding of first aid kits. U. S. v. 97 Kits * * * (F. D. C. No. 30746. Sample No. 5007-L.)

LIBEL FILED: March 14, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about August 2, 1950, by the Kiffe Sales Co., from New York, N. Y.

Product: 97 first aid kits, each kit containing a plastic tube of 6 5 mg. amphetamine sulfate tablets, a plastic tube of 8 wound tablets, a plastic tube of 12 atabrine tablets, and a glass vial of iodine, at Boston, Mass.

Examination showed that many of the items were undergoing deterioration. The kits were made up for the use of the Armed Services during the last war and were quite old.

NATURE OF CHARGE: Adulteration. Section 501 (d), a substance containing isopropyl alcohol had been substituted for Iodine Tincture U. S. P., which does not contain isopropyl alcohol.

Misbranding, Section 502 (b) (2), the labels of the tablets in the kits failed to bear accurate statements of the quantity of the contents; Section 502 (e) (1), the label of the wound tablets failed to bear the common or usual name of the drug, namely, sulfadiazine; and, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use.

DISPOSITION: April 23, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3451. Adulteration and misbranding of epinephrine bitartrate tablets. U. S. v. Graham Chemical Co. and Dr. Samuel D. Goldberg. Pleas of nolo contendere. Fine of \$2 against company and \$50 against individual. (F. D. C. No. 28106. Sample Nos. 11257-K, 11295-K.)

Information Filed: May 17, 1951, Eastern District of New York, against the Graham Chemical Co., a partnership, Jamaica, N. Y., and Dr. Samuel D. Goldberg, a partner.

ALLEGED VIOLATION: On or about July 24, 1947, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, a guaranty to the effect that all articles comprising each shipment or other delivery made by the company to the holder of the guaranty would be neither adulterated nor misbranded within the meaning of the law.

On or about October 29, 1948, and February 24, 1949, the defendants shipped under the guaranty to Long Island City, N. Y., two lots of *epinephrine bitartrate tablets*. As originally filed, the information charged that both shipments of the drug were adulterated and misbranded, but the adulteration charge was dismissed with respect to the shipment of October 29, 1948, and the misbranding charge was dismissed with respect to the shipment of February 24, 1949.

^{*}See also No. 3450.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the product in the February 1949 shipment differed from that which it purported and was represented to possess. The label represented that each tablet contained 0.75 mgm. of epinephrine bitartrate, equivalent to 0.4 mgm. (1/166 grain) of epinephrine bitartrate, and that 1 cc. of a solution containing one tablet of the article would equal a solution containing 1 part of epinephrine bitartrate per 2,600 parts of the solution. However, each tablet of the article contained less epinephrine bitartrate than so represented, and 1 cc. of a solution containing 1 tablet of the article would equal a solution containing less than 1 part of epinephrine bitartrate per 2,600 parts of the solution.

Misbranding, Section 502 (a), the statements on the label of the article in the October shipment "Each Tablet Contains: 0.4 mgm. (1/166 grain) Epinephrine Bitartrate * * * 1 tablet in 1 cc. equals 1:2600 Solution" were false and misleading since the product contained less epinephrine bitartrate than stated and implied. Further misbranding, Section 502 (a), the statement "U. S. P." on the label of the article was false and misleading since it represented that the article was a drug the name of which is recognized by the United States Pharmacopoeia, whereas the article was not a drug the name of which is recognized by the United States Pharmacopoeia.

DISPOSITION: May 25, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$2 against the partnership and \$50 against the individual.

3452. Adulteration and misbranding of Ido-Pheno-Chon. U. S. v. 11 Cases

* * * Motion for removal denied (94 F. Supp. 925). Consent decree
of condemnation. (F. D. C. No. 27921. Sample No. 50524-K.)

LIBEL FILED: November 18, 1949, District of Oregon.

ALLEGED SHIPMENT: On or about August 19, 1949, by the Pyo-Gon Laboratories, from Los Angeles, Calif.

PRODUCT: 11 cases, each containing 12 6-ounce bottles, of *Ido-Pheno-Chon* at Portland, Oreg.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess, namely, "bacteriostatic solution."

Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not bacteriostatic: (Bottle label) "For Dental and Oral Use Bacteriostatic Solution" and (carton label) "For Dental and Oral Use Bacteriostatic Solution * * * to markedly inhibit certain bacterial infections * * * Ido-Pheno-Chon, due to its high bacterio-static properties, aids in the management of gum infection and in control of other mouth infections. Its effectiveness has been attested in actual case histories."

DISPOSITION: On or about February 9, 1950, the Pyo-Gon Laboratories, claimant, filed a motion for removal of the libel action to another jurisdiction; and on August 31, 1950, after consideration of the briefs and arguments of counsel, the court handed down the following opinion in denial of the motion:

FEE, Chief Judge: "A libel was commenced against certain goods shipped into this District from a point within the Southern District of California and found here. The charge is misbranding and adulteration. The goods were seized. Thereupon, claimant made a motion to transfer the cause to the Southern District of California or, if that be denied, to a district adjacent thereto.

967728-51-2

"The problem raised by the motion is assumed to be of easy solution. For a District Court burdened with work, any move to remove a cause elsewhere is to be welcomed as a relief of some of the burden. But there is always the serious question of power. Simply because the final problem is one of place of trial, it is generally believed only venue is involved. But actually there is a transfer of jurisdiction. This Court, by virtue of the filing of the libel, now has jurisdiction of the proceeding. By the seizure, this Court has juris-

diction of the res. "The District Courts of the United States were not created as units of one vast continental judicial system. Each has been organized by special statute as a court of the judicial system of the state in which it exercises power. A District Court is a separate entity. No District Court has jurisdiction crossing a state boundary. By virtue of these limitations, the transfer of any cause from one district to another is a question of power. No District Court has such inherent authority. There must be an express statutory grant as a condition precedent to the initiation of the transfer. Furthermore, every essential factor must be present or the District Court to which the papers are sent will not acquire jurisdiction.² Unquestionably, these difficulties become manifold when a res is within the possession of the court where the libel is filed.

"The question of whether a res once under the jurisdiction of one District Court can be validy transferred to another is, of course, fundamental. It strikes at the proposition that local suits, such as mortgage foreclosure and real actions, can be tried only in the courts of the state where the real property is situate.3 If this barrier is swept away for mere convenience of some Californía corporation, local autonomy will end. This will no longer be an indivisible union of indivisible states.

"However this may be, the existence of the power of transfer is jurisdictional

and may only be exercised in strict accordance with the statutory grant.
"Title 21 U. S. C. A. § 334 (a) gives the power to transfer a single libel action where the charge is misbranding. But the charge here is adulteration and misbranding. There is no authority here for transfer.

"Title 28 U. S. C. A. § 1404 (a) gives power to transfer any civil action to any district where it might have been brought. This action could only have been brought in Oregon, because here alone was the res 'found.' Title 21 U.S.C.A. § 334 (a); Title 28 U. S. C. A. § 1395 (d), New Judicial Code.

"Title 28 U. S. C. A. § 1404 (b) provides for transfer of an in rem proceeding from one division of the same district to another division. This is, of course, permissible because the same District Court retains jurisdiction of the res. The provision would be of doubtful validity otherwise. But the language does not permit transfer of a res in judicial custody of one District Court to another, as is sought here."

"Since no statutory provision exists, this Court is without power to initiate the transfer. No other District Court has jurisdiction to hear the cause if transfer issue.

"The motion is denied."

On February 12, 1951, the Pyo-Gon Laboratories having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

³ Brown vs. Heinen, 61 F. Supp. 563, 564.
² Petition of Mundorff, 8 F. R. D. 7, 9.
³ In such cases, the want of jurisdiction of the subject matter cannot be waived by appearance or consent. Thus in Ellenwood vs. Marietta Chair Co., 158 U. S. 105, the Court says: "The entire cause of action was local. The land alleged to have been trespassed upon being in West Virginia, the action could not be maintained in Ohio. The Circuit Court of the United States, sitting in Ohio, had no jurisdiction of the cause of action, and for this reason, if for no other, rightly ordered the case to be stricken from its docket, although no question of jurisdiction had been made by demurrer or plea."

⁴ United States vs. 74 Cases, Each Containing 48 Cans of C. C. Brand Oysters, 55 F. Supp. 745, 746.

5 United States vs. 23 Gross Jars, More or Less, of Enca Cream, 86 F. Supp. 824, 825.

3453. Adulteration and misbranding of pentobarbital sodium. U. S. v. 10 Drums * * * (F. D. C. No. 30672. Sample No. 17103-L.)

LIBEL FILED: March 5, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about January 24, 1951, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 10 5-pound drums of pentobarbital sodium at Los Angeles, Calif. Examination showed that the product contained not more than 92.2 percent pentobarbital sodium, calculated on the anhydrous basis. The Pharmacopoeia provides that pentobarbital sodium shall contain not less than 98.5 percent of pentobarbital sodium, calculated on the anhydrous basis.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "pentobarbital sodium," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium; and its strength differed from, and its quality and purity fell below, the official standard since it contained a lesser proportion of pentobarbital sodium and a greater proportion of impurities than that permitted by the official compendium.

Misbranding, Section 502 (a), the label statement "Pentobarbital Sodium U. S. P." was false and misleading as applied to an article which did not conform to the requirements of the United States Pharmacopoeia.

DISPOSITION: May 22, 1951. Strong, Cobb & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

3454. Adulteration and misbranding of Synthomenthol crystals. U. S. v. 5

Cans * * * (F. D. C. No. 29503. Sample No. 14970-K.)

LIBEL FILED: July 25, 1950, Western District of Michigan; libel amended July 27, 1950.

ALLEGED SHIPMENT: On or about August 30, 1949, by the Bendix Chemical Corp., from New York, N. Y.

PRODUCT: 5 6-pound cans of Synthomenthol crystals at Kalamazoo, Mich.

LABEL, IN PART: "Synthomenthol Crystals Pure."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), 1-methyl-3-dimethyl-cyclohexanol-5 had been substituted for menthol U. S. P. synthetic, which the article was represented to be.

Misbranding, Section 502 (a), the label designation "Synthomenthol Crystals" was misleading as applied to an article which was not synthetic menthol. DISPOSITION: June 1, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3455. Misbranding of Fountain of Youth. U. S. v. Da-Vi Cantubra Laboratory (Fountain of Youth and Fountain of Youth Mfg. Co.), David W. Holliday, and Viola G. Giering. Pleas of guilty. Fine of \$1,000 against laboratory suspended; fine of \$1,000 against Defendant Holliday and \$500 against

^{*}See also Nos. 3451-3454.

Defendant Giering. Each individual also sentenced to 1 year in prison; prison sentences suspended and each individual placed on probation. (F. D. C. No. 29992. Sample Nos. 47114-K, 47790-K, 47791-K, 52983-K, 53225-K.)

INFORMATION FILED: January 4, 1951, Southern District of Ohio, against the Da-Vi Cantubra Laboratory, a partnership, formerly trading under the name of Fountain of Youth and the Fountain of Youth Mfg. Co., at Dayton, Ohio, and against David W. Holliday and Viola G. Giering, partners in the partnership.

ALLEGED SHIPMENT: On or about May 9, and 21 and September 3, 1949, and January 9, 1950, from the State of Ohio into the States of Pennsylvania, Texas, West Virginia, and Indiana.

Product: Examination showed that the product was a yellow semi-solid mass with an aromatic odor, consisting essentially of oily material, including mineral oil, saccharin, and sodium chloride, with a portion of the product also containing sodium bicarbonate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Fountain of Youth * * * Recommended as a Treatment" and "Fountain of Youth * * * Good Enough For A King" were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of hardening of the breast, hardening of the stomach, tumor of the uterus, female trouble, arthritis, after effects of infantile paralysis, fissure of the rectum, goiter, pus in the lungs, open legs, malaria fever, spinal meningitis, kidney and bladder trouble, stricture of the urinal tract, nervous, fluttering heart, piles, hemorrhoids, ulcerated stomach, gastric acidity, kidney stones, colds, colonitis, asthma, stiff joints and muscles, hemorrhage of the mouth, spastic paralysis, swollen feet, running ears, prostate gland trouble, and sugar diabetes; that the article would be efficacious in the prevention of colds; that it would aid digestion and would help one's eyesight; that it would build up the blood; that it would enable one to become free from disease; that it would be efficacious to remove gallstones and black scales in the gall bladder; that it would be efficacious in the removal of worms in children; that it would be efficacious to relieve a rash on the body and an itching of the skin; that it would enable one to keep his blood in good condition; that it would help one ward off colds and other diseases; and that it would be efficacious in the cure, mitigation, and treatment of shakiness, rheumatism, gall bladder trouble, nervousness, low blood pressure, pin worms, ulcers, dyspepsia, lumbago, bloating, sour stomach, gas in the bowels and stomach, scaly, rough, and dry skin, aches and pains, stomach trouble, neuritis, high blood pressure, tuberculosis, diarrhea, and cancer. The article would not be efficacious for the purposes represented, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: May 24, 1951. Pleas of guilty having been entered, the court imposed a fine of \$1,000 against the partnership, \$1,000 against Defendant Holliday, and \$500 against Defendant Giering. However, the fine against the partnership was suspended. In addition, the court sentenced both individuals to 1 year in prison, but suspended the execution of the prison sentences and placed the individuals on probation, conditioned that they do not again engage in any kind of a drug business.

- 3456. Misbranding of crude black molasses. U. S. v. Clinton D. Keagy and John S. Riley, Jr. Pleas of nolo contendere. Fine of \$1,000 against each defendant, plus costs. (F. D. C. No. 30049. Sample Nos. 7789-K, 69196-K, 69375-K.)
- Information Filed: February 13, 1951, Western District of Pennsylvania, against Clinton D. Keagy and John S. Riley, Jr., New Castle, Pa.
- ALLEGED SHIPMENT: On or about November 23, 1949, by Clinton D. Keagy, from the State of Pennsylvania into the State of New York; and on or about May 22 and June 15, 1950, by Clinton D. Keagy and John S. Riley, Jr., from the State of Pennsylvania into the States of New York and Ohio.
- NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a booklet entitled "Crude Black Molasses," which accompanied the article, were false and misleading. The statements represented that the article would be effective in the prevention and treatment of cancer, paralytic strokes, arthritis, ulcers, dermatitis eczema, psoriasis, high blood pressure, angina pectoris, weak heart, constipation, colitis, varicose veins, mental dullness, tuberculosis, infections, sinus trouble, pernicious anemia, anemia, bladder trouble, difficult urination, gallstones, nervousness, menopausal difficulties, erysipelas, pyorrhea, premature graying of the hair, and brittle and crumbling finger nails. The article would not be effective in the prevention and treatment of such diseases and conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

- DISPOSITION: May 21, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$1,000, plus costs, against each defendant.
- 3457. Misbranding of Color-Therm device. U. S. v. 4 Devices, etc. Tried to the court. Order of dismissal. Reversed and remanded upon appeal (176 F. 2d 652). Decree of condemnation. Affirmed upon appeal (187 F. 2d 1005). (F. D. C. No. 26630. Sample Nos. 55166-K to 55168-K, incl.)
- LIBEL FILED: March 7, 1949, Western District of Oklahoma; libel amended on April 27, 1949.
- ALLEGED SHIPMENT: During July 1946 and on or about September 9, 1948, by Dr. Fred Gerkey, from Mission, Kans., via the automobile of Franklin D. Lee; and on or about January 2, 1949, by Dr. Fred Gerkey, from Mission, Kans., via common carrier.
- PRODUCT: 4 Color-Therm devices, together with 9 applicators, 15 cabinets, and 14 transformers, at Britton, Okla. The devices were accompanied by printed sheets headed "Instructions." The printed sheets were copies which had been prepared by Franklin D. Lee, from an original which had been supplied to him by Dr. Gerkey.
- NATURE of CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the devices, namely, in the above-mentioned printed sheets, were false and misleading. The statements represented and suggested that the devices were effective in the treatment of any disease condition, and, in particular, disorders of the liver and eyes, female trouble, asthma, nervousness, and sinus trouble. The devices were not effective in the treatment of such disease conditions. The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: Franklin D. Lee, claimant, filed a plea of intervention, alleging that the printed sheets did not constitute labeling of the devices. The case came up for trial before the court on April 27, 1949, and after the introduction of evidence relating to the preparation and shipment of the circulars, the court, upon motion of the claimant, ordered that the libel be dismissed.

An appeal was taken by the Government to the United States Court of Appeals for the Tenth Circuit, and on July 27, 1949, the following opinion was handed down:

PHILLIPS, Chief Judge: "This is an appeal from an order dismissing an action to condemn instituted under the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. §§ 301-392, 52 Stat. 1040, as amended by the Act of June 24, 1948, 62 Stat. 582).1

"The action was commenced by filing a libel seeking the seizure and condemnation of 4 devices, 9 applicators, 15 cabinets, 14 transformers and certain documents designated as instructions. The information alleged that the articles were devices as defined in 21 U. S. C. A. § 321 (h) and were misbranded within the meaning of 21 U. S. C. A. § 352 (a), while held for sale after shipment in interstate commerce, by reason of false and misleading labeling claims that the devices were effective in the treatment of any disease and, in particular, of disorders of the 'liver, eyes, female trouble, asthma, nervousness and sinus trouble.'

"Each device consists of a wooden cabinet with a series of tubes on top thereof for producing colored lights similar to neon lights, together with electrical connections needed to operate them and an accessory applicator consisting of two tubes, a handle and an extension cord to connect it with the main device. The user is instructed to place his bare feet on the cabinet tubes, elevate his head so that he can see the colors, and to massage with the applicator tubes the area of the body affected.

"Lee, a salesman of the devices, filed a petition in intervention in which he alleged that he was the owner of the seized devices; that they were seized without a search warrant; that the instructions did not physically accompany the devices in interstate commerce, and were not affixed to the devices while in Lee's possession, and that he had not shipped the instructions in interstate

"The case came on for trial without a jury. Lee and his counsel admitted that the devices and applicators had been transported in interstate commerce into the State of Oklahoma.

"The evidence established that in February, 1949, Lee, at Britton, Oklahoma, gave inspectors of the Food and Drug Administration one copy each of two instructions; that other copies were in Lee's possession; that the copies were typed in Oklahoma from an original instruction circular furnished to Lee by Dr. Fred Gerkey of Mission, Kansas, and were to be used in connection with the sale of the devices; that it was Lee's practice when he made a sale of one of the devices to fold a copy of one of the instructions and place it under the tubes in the device before delivering it to the purchaser.

"Before the United States had an opportunity to introduce medical testimony to establish that the instructions contained false and misleading statements concerning the therapeutic value of the devices, the court held that since the instructions did not move in interstate commerce, there was no false labeling within the meaning of the Act.

"The pertinent provisions of the Act read as follows:

§ 301 (m). The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [21 U. S. C. A. 321 (m)]. § 304 (a). Any article of . . . device, . . . that is . . . misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce

¹ Hereinafter called the Act.

. . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . . [21 U. S. C. A. 334 (a), as amended].

§ 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular. [21 U. S. C. A. 352 (a)].

"It was not necessary that the instructions be physically attached to the devices. They accompanied such devices within the meaning of § 301 (m), supra. In Kordel v. United States, 335 U. S. 345, the court said:

One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.

"Here, the devices and instructions for the use thereof were in Lee's possession and when a sale was effected the device and instructions were delivered simultaneously.

"The devices were misbranded by Lee while held for sale after shipment in

interstate commerce.

"The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer, and the Act embraces misbranding while held for sale after shipment in interstate commerce.2

'In United States v. Sullivan, 332 U.S. 689, 697, the court held that the Act, so construed, does not exceed the constitutional power of Congress under the

commerce clause or invade the powers reserved to the states.

"Lee's contention that review should have been sought by writ of error rather than appeal is without merit. Appeals were substituted for writs of error by the Act of January 31, 1928, 45 Stat. 54.

"The Judgment is reversed and the cause remanded for further proceedings

not inconsistent with this opinion."

Following the remanding of the case to the United States District Court for the Western District of Oklahoma, a motion for summary judgment was made on behalf of the Government.

On April 3, 1950, the court sustained such motion on the ground (1) that the devices and the labeling involved were identical with the devices called Cosmo-Light and their labeling, which were involved in a previous seizure action against the device and a criminal prosecution of Dr. Fred Gerkey (reported in notices of judgment on drugs and devices, Nos. 2388 and 2437); and (2) that the issue of misbranding which was raised in the afore-mentioned cases was decided favorable to the Government and was therefore res judicata. The court, therefore, ordered that the devices and their parts be condemned and that the United States marshal deliver such devices and parts to the Food and Drug Administration.

This judgment was appealed to the United States Court of Appeals for the Tenth Circuit, and on March 12, 1951, the following opinion was handed down by that court:

PHILLIPS. Chief Judge: "This is an action to condemn certain devices, instituted under the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended by the Act of June 24, 1948, 62 Stat. 582, 21 U. S. C. A. §§ 301–392.' "The devices are called 'Color-Therm.' Each consists of a cabinet, a series

of tubes mounted thereon which produce colored lights similar to neon lights,

Hereinafter called the Act.
 United States v. Sullivan, 332 U. S. 689, 696-697.
 See also McDermott v. Wisconsin, 228 U. S. 115, 131.

an applicator attachable to the cabinet by an extension cord and consisting of a handle and two tubes similar to those described above, and electrical

accessories and connections for the operation of the device.

"The action was commenced by filing a libel of information. The libel alleged the Color-Therms to be devices as defined in 21 U. S. C. A. § 321 (h) and that they were misbranded within the meaning of 21 U. S. C. A. § 352 (a), while held for sale after shipment in interstate commerce, by reason of false and misleading claims in certain documents designated as instructions, which accompanied the devices, that the devices were effective in the treatment of any disease, and particularly in disorders of the 'liver, eyes, female trouble, asthma, nervousness and sinus trouble.'

"Lee, a salesman of the devices, filed a petition in intervention in which he alleged that the instructions seized with the devices did not physically accompany the devices in interstate commerce and were not affixed to or connected with the devices while they were in his possession; that prior to the seizure of the devices the use of such instructions had been abandoned and new and appropriate circulars had been substituted therefor; and that he had not shipped the instructions in interstate commerce. He did not deny that the representations made in the instructions were false and misleading, or that, prior to such alleged abandonment, the instructions had accompanied the seized devices while they were held by him for sale after shipment thereof in interstate commerce.

"An investigation of the devices and instructions was made by agents of the Food and Drug Administration on February 7 and 8, 1949. The seizure

took place shortly after March 7, 1949.

"The case came on for hearing and Lee admitted that the devices had been shipped in interstate commerce and were held for sale by him after such shipment, and that assembled devices were kept and displayed for sale at his place of business, which was a room in his house, and that he also kept in such room copies of the instructions. One of the instructions was introduced in evidence. Lee admitted its authenticity. The instructions direct the user to place his bare feet on the cabinet tubes, position his head so that he can see the colors, and massage with the applicator tubes the area of the body he desires to treat. The evidence established that on February 7, 1949, Lee, at Britton, Oklahoma, gave inspectors of the Food and Drug Administration one copy of the instructions; that other copies were in Lee's possession; that the copies were typed in Oklahoma from an original instruction circular furnished to Lee by Fred Gerkey of Mission, Kansas, and were used by Lee in connection with the sale of the devices; that it was Lee's practice when he made a sale of one of the devices to fold one of the instructions and place it under the tube of the device before delivering it to the purchaser. When it appeared that the challenged instructions had not moved in interstate commerce, the trial court held that there was no false labeling within the meaning of the Act and dismissed the proceeding. On appeal we reversed. See United States v. Four Devices, 10 Cir., 176 F. 2d 652. We held that it was not necessary that the instructions be physically attached to the devices; that the instructions accompanied the devices within the meaning of § 301 (1), supra, if they supplemented or explained the devices, and that in such a situation textual relationship, rather than physical attachment is the significant fact.3 We further held that the Act embraces the misbranding of a device while held for sale after shipment in interstate commerce.

"On remand the trial court sustained a motion of the United States for summary judgment. In support of the motion, in addition to the pleadings in the proceeding, the United States submitted: a certified copy of a libel of information filed in the United States District Court for the Southern District of California, Central Division, and thereafter transferred to the Western District of Missouri, against a like device; answer of Fred Gerkey filed therein; and the judgment entered in that cause adjudging the devices misbranded by a set of instructions substantially identical with those involved in the instant action and ordering condemnation of the devices and instructions; and an affidavit made by Lee on February 8, 1949. The affidavit averred: that Lee was the Oklahoma distributor for Fred Gerkey, who makes the devices; that

² Hereinafter called instructions.

³ See Kordel v. United States, 335 U. S. 345, 350.

he acted upon Gerkey's instructions; that the instructions were brought to Oklahoma City by Gerkey on or about July 15, 1948; that he had additional copies of the instructions typewritten, and that the devices or the unassembled parts thereof were shipped to him in Oklahoma from points outside the State of Oklahoma. Lee admitted that the instructions were false and

misleading.

"From the foregoing, other than the evidence introduced at the original hearing, the following facts were established without contradiction and no issue existed with respect thereto, namely: The devices had been shipped in interstate commerce and were thereafter held for sale by Lee; the original set of instructions were transported in interstate commerce; from those original instructions typewritten copies were made; the instructions were false and misleading; copies of the instructions were kept by Lee in his place of business, which was a room in his house, where the assembled devices were kept and displayed for sale; the instructions explained the devices, directed the manner of using them to cure disease and were textually related to the devices; prior to the seizure and while the devices were held for sale after shipment in interstate commerce, the false and misleading instructions accompanied the devices; Gerkey was the owner of the devices; and Lee acted as the agent of Gerkey and followed Gerkey's instructions.

"Therefore, if any issue of fact remained, it arose because of the allegation by Lee in his intervention that sometime before the seizure Lee had abandoned

the use of the false and misleading instructions.

"Section 334 (a), supra, provides that any device that is 'misbranded when introduced into or while in interstate commerce or while held for sale * * * after shipment in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.' [Italics added.]

"Once a device is misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce, it is subject to seizure at any time, and the fact that at the time of seizure, the false label is not upon the device or does not accompany the device does not purge the device of its prior false labeling or render it immune from seizure

and condemnation.4"

3458. Misbranding of violet ray device. U. S. v. 2 Cases * * *. (F. D. C. No. 30801. Sample No. 3858-L.)

LIBEL FILED: Between March 2 and April 24, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about July 24, 1950, by Master Appliances, Inc., from Marion, Ind.

PRODUCT: 2 imitation leather cases, each containing a violet ray device, a general electrode, a rake electrode, a throat electrode, and circulars entitled "The Master High Frequency Violet Ray," "The Master High Frequency Violet Ray A Professional Aid to Health and Beauty," and "Directions For Operating," at Baltimore, Md.

Examinations showed that the product consisted essentially of Geissler tubes of various shapes with a transformer assembly to activate them, designed to apply an intermittent ray discharge to the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. The statements represented and suggested that the device would produce pleasing, invigorating, and corrective effects; that it would be effective as a general treatment by stimulating the circulation; that it would be effective for beauty, health, and strength; that it would be effection in the treatment of rheumatic pain in the shoulder,

⁴ United States v. Various Quantities of Articles of Drug, D. C. 83 F. Supp. 882, 887; United States v. 1 Dozen Bottles, etc., 4 Cir., 146 F. 2d 361, 363. See also, United States v. Olsen, 9 Cir., 161 F. 2d 669, 671; United States v. 52 Drums Maple Syrup, 2 Cir., 110 F. 2d 914, 915; United States v. Two Bags, etc., 6 Cir., 147 F. 2d 123, 128.

nervous disorders, rheumatism, lumbago, and neuritis; that it would produce a sedative or quieting effect and establish a normal equilibrium of the nervous system; that it would relieve painful sensations; that it would be efficacious as a stimulant and tonic; that it would be efficacious for facial, body, spinal, and scalp treatments; that it would stimulate the hair; that it would be efficacious for treatment of the eyes and ears; that it would be efficacious in the treatment of cystitis, strictures, gonorrhea, and prostate and vaginal troubles; that it would promote circulation; that it would aid beauty and health by gently stimulating the flow of blood; that it would be helpful in relieving pain and congestion and in restoring good health and vigor; that it would be helpful in removing facial blemishes and in promoting a'clear, healthful complexion; and that it would aid in the removal of dandruff and assist in stopping falling hair. The device was not an effective treatment for the conditions stated and implied, and it was not capable of producing the effects claimed.

DISPOSITION: April 24, 1951. Default decree of condemnation. The court ordered that the devices be released to the Food and Drug Administration.

3459. Misbranding of Duframe Anal Tubette. U. S. v. 5,000 Devices, etc (F. D. C. No. 30250. Sample No. 58803-K.)

LIBEL FILED: November 21, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On various dates between April 14 and October 21, 1948, from Detroit, Mich.

PRODUCT: 5,000 devices known as *Duframe Anal Tubette* at Chicago, Ill., in possession of the Duframe Tubette Co. Some of the devices were unlabeled, and others had been packed and labeled in part by the consignee. They were accompanied by a number of copies of leaflets entitled "About Gas * * * About Constipation" and "Instructions," a testimonial letter signed "Mrs. Anne Schwab," and form letters starting "Thank you for your inquiry" and "Thank you for your letter and order."

The device consisted of a hollow rubber tube about 80 millimeters long and 14 millimeters outside diameter. The inside diameter was about 8 millimeters at one end, constricted to about 3 millimeters at the other end. The tube was bent at a right angle near the constricted end.

RESULTS OF INVESTIGATION: A copy of each leaflet and testimonial was packed with each device, and the form letters were sent to interested persons.

LABEL, IN PART: (Carton) "Duframe Anal Tubette."

Nature of Charge: Misbranding, Section 502 (a), certain statements in the accompanying leaflets and letters were false and misleading. The statements represented and suggested that the device was effective in the relief of dizziness, headache, pain in the abdomen and other parts of the body, bloat, swelling due to gas, and chronic constipation and gas pains due to intestinal disorders or organic complaints; that the device was effective in regulating the bowel, normalizing the bowel, and preventing constipation; and that the device would help release toxic poisons. The device would not be effective for the purposes represented. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 6, 1951. The Duframe Tubette Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for the purpose of bringing them into compliance with the law, by destroying the existing labeling

and advertising material and relabeling the devices, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3460. Misbranding of Treet L-C, Treet Vapo Spray, Treet Coryza Inhibitor, and Treet Powders Nico-Phen. U. S. v. Hilltop Farm Feed Co. and Frank E. Moore. Pleas of guilty. Individual defendant fined \$500 on count 1; imposition of sentence on remaining counts against individual suspended, and he was placed on probation for 3 years. No sentence imposed against company. (F. D. C. No. 28129. Sample Nos. 25577-K, 25904-K, 44564-K, 44565-K.)

Information Filed: November 17, 1950, District of Minnesota, against the Hilltop Farm Feed Co., a corporation, Minneapolis, Minn., and Frank E. Moore, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about September 25 and December 24, 1948, and February 8 and 9, 1949, from the State of Minnesota into the States of Wisconsin and North Dakota.

PRODUCT: Analysis disclosed that the *Treet L-C* consisted of a copper-colored solution containing hydrochloric acid, copper sulfate, and organic nitrogenous compounds (sulfanilamide derivatives); that the *Treet Vapo Spray* consisted essentially of a milky emulsion containing nonvolatile fatty material, formal-dehyde, and methyl salicylate; that the *Treet Coryza Inhibitor* contained sulfathiazole sodium; and that the *Treet Powders Nico-Phen* consisted essentially of nicotine, phenothiazine, and phenolphthalein.

LABEL, IN PART: "Treet L-C [or "Vapo Spray." "Coryza Inhibitor," or "Powders Nico-Phen"] Treet Laboratories Division of Hilltop Farm Feed Co."

NATURE of CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the Treet L-C would be efficacious in the prevention and treatment of avian leukosis complex, including range paralysis, leukemia, and various neoplastic diseases; that the Treet Vapo Spray would be efficacious in the prevention of coryza (colds) and roup in poultry; that the Treet Coryza Inhibitor would be efficacious in the treatment of roup in poultry; and that the Treet Powders Nico-Phen would be efficacious to remove all species of roundworms and tapeworms in poultry. The articles would not be efficacious for the purposes represented.

DISPOSITION: May 4, 1951. Pleas of guilty having been entered, the court imposed a fine of \$500 on count 1 against the individual defendant, but suspended the imposition of sentence on the remaining 3 counts and placed him on probation for 3 years. No sentence was imposed against the company.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3441 TO 3460

PRODUCTS

N. J	. No.			N	. J. No.
Amytal tablets	3442	Cream,	estrogenic		3449
Anal Tubette, Duframe	3459	Desoxyr	Hydrochloride	tablets_	3446,
Benzedrine Sulfate tablets 3441,	3442				3447
Color-Therm device1	3457	Devices		¹ 3457	7-3459

^{1 (3457)} Seizure contested. Contains opinions of the court.

N.	J. No.	N.	J. No.
Dexedrine Sulfate tablets 3441	-3443	Phenobarbital tablets 3442	-3444
Diethylstilbestrol tablets	3443	Synthomenthol crystals	3454
Duframe Anal Tubette	3459	Thyroid tablets 3442	-3445
Eden Creme	3449	Treet L-C, Treet Vapo Spray,	
Epinephrine bitartrate tablets	3451	Treet Coryza Inhibitor, and	
Estrogenic substance	3449	Treet Powders Nico-Phen	3460
First aid kits	3450	Triazoline tablets	3447
Fountain of Youth	3455	Tricombisul tablets	3445
Ido-Pheno-Chon	3452	Veterinary preparations	3460
Iodine, tincture of	3450	Violet ray device	3458
Molasses, black, crude	3456	Wound tablets	3450
Pentobarbital sodium	3453		
capsules 3445	-3448		
SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS			

N.	J. No.	N.	J. No.
Anderson, E. R., Sr.:		Fountain of Youth Mfg. Co. See	
Benzedrine Sulfate tablets and		Da-Vi Cantubra Laboratory.	
Dexedrine Sulfate tablets	3441	Gerkey, Dr. Fred:	
Bendix Chemical Corp.:	-	Color-Therm device	¹ 3457
Synthomenthol crystals	3454	Goldberg, Dr. S. D.:	
Captivante Labs., Inc.:		epinephrine bitartrate tablets_	3451
Eden Creme	3449	Graham Chemical Co.:	
Charleston Drug Co.:		epinephrine bitartrate tablets_	3451
Desoxyn Hydrochloride tablets		Harp, F. C.:	,
and pentobarbital sodium		Desoxyn Hydrochloride tab-	
capsules	3446	lets and pentobarbital so-	
Claybaugh, H. L.:		dium capsules	3446
thyroid tablets, pentobarbital		Hayden, D. M.:	
sodium capsules, and Tri-		pentobarbital sodium capsules_	3448
combisul tablets	3445	Hilltop Farm Feed Co.:	
Da-Vi Cantubra Laboratory:		Treet L-C. Treet Vapo Spray.	
Fountain of Youth	3455	Treet Coryza Inhibitor, and	
Duframe Tubette Co.:	0.450	Treet Powders Nico-Phen	3460
Duframe Anal Tubette	3459	Jenkins, H. C.:	
Eckerd Drug & Notion Co.: Benzedrine Sulfate tablets and		Desoxyn Hydrochloride tab-	
Dexedrine Sulfate tablets and Dexedrine Sulfate tablets	3441	lets, Triazoline tablets, and	
Fadely, W. L.:	9441	pentobarbital sodium cap-	
pentobarbital sodium capsules_	3448	sules	3447
Fadely's Drug Store No. 1. See	9770	Keagy, C. D.:	
Fadely, W. L.		crude black molasses	3456
Fisher Drug Co.:		Kiffe Sales Co.:	
Desoxyn Hydrochloride tab-		first aid kits	3450
lets, Triazoline tablets, and	11.0	Latimer, Hugh:	
pentobarbital sodium cap-		thyroid tablets and phenobar-	
sules	3447	bital tablets	3444
Fountain of Youth. See Da-Vi		Latimer Drug Co. See Latimer,	
Cantubra Laboratory.		Hugh.	

¹ (3457) Seizure contested. Contains opinions of the court,

	N. J. No.	N.	J. No.
Lee, F. D.:		fate tablets, and phenobar-	
Color-Therm device	- ¹ 3457	bital tablets	3443
Master Appliances, Inc.:		Phillips Bros. Drug Co. See	
violet ray device	_ 3458	Phillips, W. D.	
Moore, F. E.:		Potts, C. F.:	
Treet L-C, Treet Vapo Spray	7,	Benzedrine Sulfate tablets and	
Treet Coryza Inhibitor, an	d	Dexedrine Sulfate tablets	3441
Treet Powders Nico-Phen_	_ 3460	Pyo-Gon Laboratories:	
Moreland, A. C.:		Ido-Pheno-Chon	3452
thyroid tablets, Dexedrine Su	l-	Riley, J. S., Jr.:	
fate tablets, Benzedrine Su	1-	crude black molasses	3456
fate tablets, phenobarbita	ıl	Strong, Cobb & Co., Inc.:	
tablets, and Amytal tablets	3442	pentobarbital sodium	3453
Phillips, W. D.:		Treet Laboratories. See Hilltop	
thyroid tablets, diethylstilbes	3-	Farm Feed Co.	
trol tablets Devedrine Su	1-		

^{1 (3457)} Seizure contested. Contains opinions of the court.



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

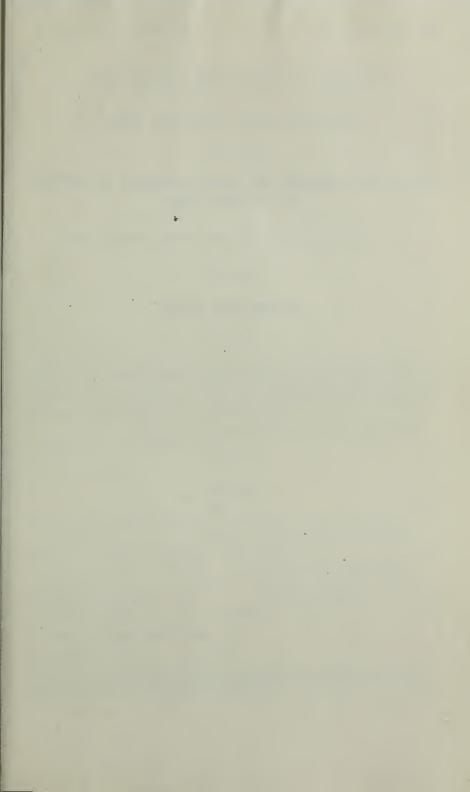
Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year







FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3461-3480

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

Charles W. Crawford, Commissioner of Food and Drugs.
Washington, D. C., November 7, 1951.

CONTENTS*

Page	Page
New drug shipped without effective	Drugs and devices actionable be-
application 456	cause of false and misleading
Drugs and devices actionable be-	claims 462
cause of failure to bear ade-	Drugs actionable because of failure
quate directions or warning	to bear a label containing an
statements 457	accurate statement of the
Drug actionable because of contam-	quantity of the contents 468
ination with filth 459	Index 468
Drugs and devices actionable be-	
cause of deviation from official	
or own standards 459	

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3464-3466; omission of, or unsatisfactory, ingredients statements, No. 3465; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3465.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3461. TB-1 tablets (4-Acetylaminobenzaldehyde Thiosemicarbazone). U. S. v. 36,650 Tablets * * *. (F. D. C. No. 31050. Sample No. 21635-L.)

LIBEL FILED: On or about April 11, 1951, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about March 16, 1951, by B. L. Lemke & Co., Inc., from Lodi, N. J.

PRODUCT: 36,650 TB-1 tablets (4-Acetylaminobenzaldehyde Thiosemicarbazone) contained in 37 bottles at New Orleans, La.

LABEL, IN PART: "TB-1 Tablets (4-Acetylaminobenzaldehyde Thiosemicarbazone) Caution: Considered A New Drug Within The Meaning Of The Food, Drug, and Cosmetic Act. Limited by Federal Law To Investigational Use Only Or For Export. For Chemical and Manufacturing Use Only. Warranted Only As To Identity, Quality And Quantity."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: May 18, 1951. Default decree of condemnation and destruction.

3462. 4-Acetylaminobenzaldehyde Thiosemicarbazone (powder). U. S. v. 1 Drum

* * *. (F. D. C. No. 30882. Sample No. 22814-L.)

LIBEL FILED: April 2, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 14, 1951, by the Persol Chemical Co., from Richmond Hill, N. Y., to Long Island City, N. Y., for shipment to Chile.

PRODUCT: 1 33-pound drum of 4-Acetylaminobenzaldehyde Thiosemicarbazone (powder) at Long Island City, N. Y.

Label, in Part: "4-Acetylaminobenzaldehyde Thiosemicarbazone New Drug for Experimental Purpose Only."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: May 24, 1951. Default decree of condemnation and destruction.

3463. P-acetylaminobenzaldehyde thiosemicarbazone (powder). U. S. v. 10 Kilograms * * * (F. D. C. No. 30863. Sample No. 24438–L.)

LIBEL FILED: April 10, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about February 27, 1951, by Cole Laboratories, Inc., from Long Island City, N. Y., to New York, N. Y., for shipment to Buenos Aires, Argentina.

PRODUCT: 10 kilograms of p-acetylaminobenzaldehyde thiosemicarbazone powder at New York, N. Y.

Labell, IN Part: "p-acetylaminobenzaldehyde thiosemicarbazone For scientific, laboratory or manufacturing use only * * * Retort Pharmaceutical Co., Inc. * * * Long Island City, N. Y. Retort Laboratory."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 1, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 3464. Misbranding of Seconal Sodium capsules, Carbrital capsules, and pentobarbital sodium capsules. U. S. v. Corner Drug Co., Inc. (Donovan Drug Co.), and Charles E. Donovan. Pleas of nolo contendere. Fine of \$250 against corporation and \$50 against individual. (F. D. C. No. 30570. Sample Nos. 80018-K to 80020-K, incl., 80282-K, 80285-K, 80296-K, 80297-K, 80301-K, 80310-K, 80318-K, 80319-K, 80359-K.)
- Information Filed: June 1, 1951, District of Massachusetts, against Corner Drug Co., Inc., trading as the Donovan Drug Co., Boston, Mass., and against Charles E. Donovan, treasurer of the corporation.
- INTERSTATE SHIPMENT: From the States of Indiana, Michigan, and New York, into the State of Massachusetts, of quantities of Second Sodium capsules, Carbrital capsules, and pentobarbital sodium capsules.
- ALLEGED VIOLATION: On or about September 1, 5, 6, 8, 11, 13, 16, 18, and 20, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged capsules contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, in addition, the Carbrital capsules contained a substance, carbromal, and the label of the capsules failed to bear the name, and quantity or proportion of such substance and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions "One at bed time" appearing in the labeling of the Seconal Sodium capsules, "One capsule at bed time" appearing in the labeling of the Carbrital capsules, and "One capsule at night" and "One at night" appearing in the labeling of a number of the repackaged pentobarbital sodium capsules were not adequate directions for use, and since the labeling of a portion of the repackaged pentobarbital sodium capsules bore no directions for use.

Disposition: June 12, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the corporation and \$50 against the individual.

- 3465. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Robert L. Mealy (Mason Pharmacy). Plea of guilty. Fine, \$300. (F. D. C. No. 29451. Sample Nos. 60670-K to 60672-K, incl., 60674-K.)
- Information Filed: September 6, 1950, Eastern District of Wisconsin, against Robert L. Mealy, trading as the Mason Pharmacy, Milwaukee, Wis.
- ALLEGED SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of Seconal Sodium capsules and Benzedrine Sulfate tablets.

ALLEGED VIOLATION: On or about September 29 and 30 and October 7 and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the Seconal Sodium capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement, "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), (1 sale) the *Benzedrine Sulfate* tablets failed to bear a label containing the common or usual name of the drug.

DISPOSITION: June 29, 1951. A plea of guilty having been entered, the court imposed a fine of \$300.

3466. Misbranding of phenobarbital tablets. U. S. v. Renton Ten Cent Drug. Plea of nolo contendere. Fine, \$1,500. (F. D. C. No. 29428. Sample Nos. 20754–K, 40808–K.)

Information Filed: January 30, 1951, Western District of Washington, against the Renton Ten Cent Drug, a partnership, Renton, Wash.

ALLEGED VIOLATION: On or about December 4, 1948, the defendant caused to be introduced into interstate commerce at Renton, Wash., for delivery to Omaha, Nebr., a quantity of *phenobarbital tablets* which were misbranded.

In addition, on or about June 2, 1949, while a number of *phenobarbital tablets* were being held for sale at the defendant's store, the defendant caused a number of the tablets to be repacked and sold without a physician's prescription, which acts resulted in the tablets being misbranded.

Nature of Charge: Misbranding, Section 502 (b) (2), the phenobarbital tablets failed to bear a label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use since the directions "Half tablet night and morning" and "One tablet as necessary" were not adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Disposition: June 7, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$1,500 against the partnership.

3467. Misbranding of Devine's Zina-Ray oil and Devine's inhaler. U. S. v. 434

Bottles, etc. (F. D. C. No. 30884. Sample Nos. 32067-L to 32070-L, incl.)

LIBEL FILED: March 30, 1951, Eastern District of Arkansas.

Alleged Shipment: On or about January 26 and February 12, 1951, by Devine's Remedies; from Chicago, Ill.

PRODUCT: 434 1-ounce bottles and 8 4-ounce bottles of *Devine's Zina-Ray oil* and 200 *Devine's inhalers* at Little Rock, Ark. The inhalers consisted of a glass tube containing cotton. The tubes were constricted at one end and were plugged with a perforated cork at the other end.

RESULTS OF INVESTIGATION: A placard entitled "The American Research and Testing Laboratories * * * Report on Clinical Test" was displayed with the articles in the store of the consignee. Sales of the articles were made on the basis of lectures given at the store by demonstrators Itasia S. Stearns and Henry C. Stearns, on behalf of the distributor, Devine's Remedies.

Label, In Part: (Bottle) "Devine's Zina-Ray Oil Contains Eucalyptus Oil, Menthol and Gum Camphor"; (device) "Devine's Inhaler."

Nature of Charge: Misbranding, Section 502 (a), certain statements on the placard were false and misleading since they represented and suggested that the articles were effective in the treatment and release of pressure, congestion, and pain due to arthritic conditions, whereas the articles were not effective for such purposes; and, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of the conditions for which they were intended by their distributor, Devine's Remedies, namely, rheumatism and spongy gums, and for overcoming nasty taste in the morning, phlegm, and mucus.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 8, 1951. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3468. Adulteration of fleaseed (Plantago) husks. U. S. v. 17 Bags * * *. (F. D. C. No. 30693. Sample No. 18760-L.)

LIBEL FILED: March 12, 1951, Southern District of Iowa.

ALLEGED SHIPMENT: On or about January 12, 1951, by L. L. Hopkins & Co., from New York, N. Y.

PRODUCT: 17 90-pound bags of fleaseed (Plantago) husks at Des Moines, Iowa.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: April 21, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3469. Adulteration and misbranding of Premestrone (conjugated estrogens).
U. S. v. 22 Bottles * * * (F. D. C. No. 30873. Sample No. 9715–L.)

LIBEL FILED: April 2, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 3, 1951, by the Doctors' Mutual Service Co., from Glendale, Calif.

Product: 22 90-tablet bottles of *Premestrone* (conjugated estrogens) at Waukegan, Ill.

Label, In Part: (Bottle) "Premestrone 0.4 mg. 90 Tablets Estrogenic Substances (Water Soluble). Also known as Conjugated Estrogens (Equine).

* * * Formulated and Distributed By Specific Bio-Chemicals Glendale, California."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 0.4 mgm. of estrogens in their water-soluble form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 0.4 mgms. of estrogens in their water soluble form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained less than the stated amount of estrogens.

DISPOSITION: May 8, 1951. Default decree of condemnation and destruction.

3470. Adulteration and misbranding of estrogenic powder. U. S. v. 2 Bottles * * *. (F. D. C. No. 30812. Sample No. 22751-L.)

LIBEL FILED: February 28, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about August 14, 1950, from Landing, N. J.

PRODUCT: 2 bottles of estrogenic powder at New York, N. Y., in possession of Tuteur Bio-Chemicals, Inc.

RESULTS OF INVESTIGATION: The label of the article at the time of seizure had been applied by Tuteur Bio-Chemicals, Inc.

LABEL, IN PART: "2272.5 grams Estrogenic Powder containing 30.9 grams water soluble conjugated estrogens expressed as Sodium Estrone Sulfate standardized at 13.9 mgm of active ingredient per gram of bulk carrier (carriers: Magnesium Oxide and Calcium Carbonate)."

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, an amount of water-soluble conjugated estrogens calculated to 13.9 mg. of sodium estrone sulfate per gram of the article.

Misbranding, Section 502 (a), the label statement "Estrogenic Powder containing * * * water soluble conjugated estrogens expressed as Sodium Estrone Sulfate standardized at 13.9 mgm of active ingredient per gram of bulk carrier" was false and misleading as applied to an article which contained only an amount of estrogenic steroids calculated as 7.8 mg. of sodium estrone sulfate per gram of the article.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 19, 1951. Default decree of condemnation and destruction.

3471. Adulteration and misbranding of oil of cedar leaf. U. S. v. 2 Tins * * *. (F. D. C. No. 30726. Sample No. 15262-L.)

LIBEL FILED: On or about April 2, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 12, 1950, by Berje Chemical Products, Inc., from New York, N. Y.

PRODUCT: 2 25-pound tins of oil of cedar leaf at Kansas City, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance other than oil of cedar leaf had been substituted in whole or in part for oil of cedar leaf.

Misbranding, Section 502 (a), the label designation "Oil Cedarleaf" was false and misleading as applied to an article that was not oil of cedar leaf."

DISPOSITION: May 21, 1951. Default decree of condemnation and destruction.

3472. Adulteration and misbranding of adhesive bandages. U. S. v. 160 Cartons

* * * (F. D. C. No. 30808. Sample Nos. 25334-L, 25335-L.)

LIBEL FILED: February 21, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 8, 1950, and January 9, 1951, by Supreme First Aid Co., Inc., from New York, N. Y.

PRODUCT: 160 cartons, each containing 36 packages, of adhesive bandages at Philadelphia, Pa.

Label, in Part: (Package) "Waterproof Supreme Six Bands Handy Adhesive Bands Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label designation "Sterilized" was false and misleading.

DISPOSITION: May 24, 1951. Default decree of condemnation and destruction.

3473. Adulteration and misbranding of oral and rectal thermometers. U. S. v. 21

Dozen * * * (and 1 other seizure action). (F. D. C. Nos. 30781,
30782. Sample Nos. 25319-L, 25320-L.)

LIBELS FILED: February 27, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 3 and 16, 1951, by Guardian Thermometer Co., Inc., from New York, N. Y.

PRODUCT: 21 dozen oral thermometers and 34 dozen rectal thermometers at Philadelphia, Pa.

Examination of 24 oral thermometers showed that 5 failed to meet the labeled standard of accuracy and that 9 failed to meet the CS1-32 requirement that the width of the engraved markings be less than the intervening spaces. Examination of 24 rectal thermometers showed that 3 failed to meet the labeled standard of accuracy; that 3 failed to meet the CS1-32 test for entrapped gas; and that 1 failed to meet the test for retreaters.

LABEL, IN PART: "Oral Clinical Thermometers" and "Globe Fever Thermometer Rectal."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the thermometers fell below that which they purported and were represented to possess.

Misbranding, Section 502 (a), the statements which appeared in the labeling of the thermometers were false and misleading as applied to articles which failed to comply with the following specifications: (Oral thermometer) "This Certifies that the enclosed thermometer bearing the above identification number has been tested on the above date at 98°, 102° and 106° F. and is correct within plus or minus 2/10 F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1-32 Department of Commerce). The enclosed thermometer is guaranteed to be of absolute accuracy * * *"; (rectal thermometer) "This thermometer has been tested, found to comply with the requirements of the Department of Commerce Commercial Standard C. S. 1-32"; and (on leaflet accompanying rectal thermometers) "This is to Certify that Self-registering Clinical Thermometer 'GT' has been examined, tested and found to meet all requirements and tests specified in the 'Commercial Standard CS1-32 for Clinical Thermometers' used by the United States Department of Commerce. 'Three point' comparisons with clinical Standard Thermometer, certified by the Bureau of Standards, Washington, D. C., showed no

variations of reading in excess of negligible tolerances of one-fifth of a degree, plus or minus. The instrument—having been properly made and seasoned is correct and should not change with age * * *."

Disposition: May 24, 1951. Default decrees of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3474. Misbranding of Braska tablets. U. S. v. 30 Dozen Bottles, etc. (F. D. C. No. 30861. Sample No. 32273-L.)

LIBEL FILED: March 26, 1951, Southern District of Illinois.

Alleged Shipment: On or about February 5, 1951, by National Package Drugs, Inc., from St. Louis, Mo.

PRODUCT: 30 dozen bottles of Braska tablets at Alton, Ill., together with a number of display cartons and paper bags.

LABEL, IN PART: "Braska Tablets Each tablet contains * * * 11/2 gr. Phenacetin, Manganese and Magnesium Salicylates, Salicylamide, Camphor Mono Bromated, Caffeine."

NATURE of CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the display cartons and the paper bags reading "Arthritis," contained statements which represented and suggested that the article was an adequate and effective remedy for arthritis. These statements were false and misleading since the article was not an adequate and effective remedy for arthritis.

Disposition: April 18, 1951. Default decree of condemnation and destruction.

3475. Misbranding of Massengill powder. U.S. v. 1,365 Jars * * *. No. 30934. Sample No. 12203-L.)

LIBEL FILED: April 20, 1951, Southern District of Ohio.

Alleged Shipment: On or about December 12, 1950, and January 15, February 15, and March 16, 1951, by the S. E. Massengill Co., from Bristol, Tenn.-Va.

Product: 551 3-ounce jars, 563 6-ounce jars, and 251 1-pound jars of Massengill powder at Cincinnati, Ohio. Analysis showed that the product consisted essentially of boric acid, alum, and carbolic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "It is suggested as an application for soft, spongy, and bleeding gums" contained in the circular entitled "Massengill Powder" enclosed with the article was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for pyorrhea, whereas it was not an adequate and effective treatment for pyorrhea.

Further misbranding, Section 502 (a), the following statements in the above-mentioned circular were false and misleading since the article was not effective for the purposes stated and implied: "* * Deodorizing the vaginal secretions * * * Maintaining the normal acidity of the vaginal tract * * * Many medical authorities agree that such cleansing, two or three times a week, serves a useful purpose * * * for deodorizing * * * for helping to maintain normal vaginal acidity * * * For maintaining normal acidity of the genital tract. Most of the disease-producing organisms which may affect the vagina cannot survive when the medium in which they live becomes sufficiently acid. Nature attempts to keep the vagina

^{*}See also Nos. 3467, 3469-3473.

acid in reaction. Massengill Powder assists Nature in this respect, and by helping maintain an acid reaction tends to suppress the growth of undesirable microorganisms. As a cleansing, physiologic douche. The use of a bland, warm, slightly acid douche is recommended two or three times each week as a cleansing wash for hygienic purposes * * * As a vaginal douche * * * Use night and morning * * *."

DISPOSITION: May 8, 1951. The S. E. Massengil Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

3476. Misbranding of Biogen products. U. S. v. 9 Biogen Kits, etc. (F. D. C. No. 30342. Sample Nos. 90412–K, 90413–K.)

LIBEL FILED: December 21, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about December 1, 1950, by Nutritional Industries, Inc., from Santa Monica, Calif.

Product: 9 Biogen kits, each kit containing 1 bottle of Formula C-A 3-90, 1 bottle of Formula EM-B 3-90, 1 bottle of Formula M-T 3-90, and 1 bottle of Formula V-T 3-90, at Seattle, Wash., together with 3 1-pint bottles and 18 8-ounce bottles of Biogen Formula No. 23 and certain accompanying written, printed, and graphic matter, namely, 25 copies of a leaflet entitled "Minerals A Very Important Factor," 75 copies of a booklet entitled "Chlorophyll the 'Green Magic,'" 12 sets of mimeographed sheets (11 pages per set) entitled "Index of Case Histories," 10 portfolios containing testimonial letters and pamphlets, 12 copies of a booklet entitled "Nutritional Industries Sales Manual," 20 portfolios entitled "Reprints from the Lee Foundation for Nutritional Research, Milwaukee, Wisconsin," 100 copies of an article entitled "Modern Miracle Men" by Rex Beach, and 10 copies of a booklet entitled "Down to Earth."

LABEL, IN PART: (Bottle and carton) "Biogen Formula No. 23 Each tablespoon (15 c.c.) contains ten milligrams Niacinamide in water base, containing highly purified water soluble Chlorophyll (Sodium Copper Chlorophyllin) 0.4% concentration and water soluble principles extracted from Alfalfa. Each cubic centimeter (c.c.) contains approximately 4.0 mg. of Sodium Copper Chlorophyllin, a water soluble salt of Chlorophyll. Directions: As a dietary source of Niacinamide, take one tablespoon (15 c.c.) in half glass of water daily. Stir well and drink, * * * Formulated By Biogen Products Co. Los Angeles, California"; (bottles in kits) "Formula C-A 3-90 Each tablet contains Calcium Lactate 8 grains (a salt of Lactic Acid), Calcium Gluconate 2 grains, Vitamin D 100 I.U. and dried water extract of alfalfa * * * There is no evidence that extract of alfalfa has therapeutic or physiologic value. Directions: As a supplementary source of calcium and vitamin D, (three tablets before morning and evening meal), six tablets will supply 60 percent of the minimum daily adult requirement of calcium and 150 percent of vitamin D. * * * Contents 540 Tablets Formulated By Biogen Products Co. Los Angeles, California"; "Formula EM-B 3-90 Contains: Vitamin B1, alpha tocopherol acetate (Vitamin E) * * * The Daily Ration of one-fourth teaspoonful (23 average drops) provides Vitamin B1: 10 Mg. (3334 USP Units) Vitamin E (alpha tocopherol acetate): 8 Mg. Net Contents 3% Fluid Ozs. (see side panels) * * * Formulated By Biogen Products Co. Los

Angeles, California * * * Directions: As a source of vitamins B_i and E, one-fourth teaspoonful daily or 23 average drops taken in a tablespoon. This amount provides 10 times the daily minimum adult requirements of vitamin B_i . The need for vitamin E in human nutrition has not been established"; "Formula M-T 3-90 Two tablets provide: Two hundred percent of the daily adult minimum requirements of Iron and two hundred percent of Iodine. * * * in a base of Montmorillonite Clay * * * dried water extract of alfalfa and 3 milligrams of Chlorophyll. The Chlorophyll is derived from Sodium Copper Chlorophyllin. There is no evidence that extract of alfalfa or chlorophyll have therapeutic or physiologic value. Directions: Two tablets with evening meal. Contents 180 Tablets * * * Formulated By Biogen Products Co. Los Angeles, California"; and

"Formula V-T 3-90 Each tablet contains:	% daily minimum requirement
Vitamin A5000 U.S.P. Units	
Vitamin D 800 U.S.P. Units	
Vitamin B ₁ 2664 U.S.P. Units	
Vitamin $G(B_2)$ 4 Mg	200%
Vitamin C1800 U.S.P. Units	300%
Vitamin K Activity0.5 Mg.	
*Calcium Pantothenate10 Mg.	
Niacinamide 10 Mg	

Sugar coated with added color from Chlorophyll and certified color * * * * Contents 90 Tablets * * * Formulated By Biogen Products Co. Los Angeles, California * * * Directions: Take one tablet daily with morning meal. *The need in human nutrition for vitamins marked with * has not been established."

Nature of Charge: Misbranding, Section 502 (a), certain statements, representations, and suggestions in the labeling of the articles were false and misleading. The labelings when read as a whole contained statements, representations, and suggestions that almost everyone is suffering from poor health; that this is a result of a deficiency of minerals and vitamins; that this deficiency is caused by depleted soil and improper processing, storage, and cooking of foods; that most of the diseases, ailments, and conditions which afflict mankind are the result of malnutrition; that the articles would be effective in toning the system, stimulating the formation of red blood corpuscles in various forms of anemia, producing miraculous results in wound healing and stimulating granulation of tissue in burns; and that the use of the article would be an adequate treatment, preventive, and cure of such diseases, ailments, and conditions as arthritis, phlebitis, leg ulcers, varicose veins, shiritis (sic) (cirrhosis), cancer of breast, loss of weight, diabetes, headaches, nervousness, skin condition, malnutrition, paralysis, warts, obesity, sinus headaches, congestion, cysts, ulcers, chest congestion, nervous breakdown, swollen ankles, stomach trouble, poor appetite, rheumatic fever, underweight, rheumatism, eye infections, enlarged heart, anemia, bleeding gums, stomach ulcers, constipation, cancer, hay fever, asthma, run-down condition, tumor, skin cancer, female trouble, high blood pressure, stroke, lack of control of right foot, heart trouble, kidney and bladder trouble, tuberculosis, allergic skin eruption, poliomyelitis, leukemia, swollen and numb leg, colds, sinus infections, impaired vision, enlarged thyroid, hemorrhoids, defective hearing, dizzy spells, pounding heart, difficulty in breathing, stiffness in joints, fatigue, poisons, impotence, low vitality, frigidity, neuritis, alopecia, diseases of the skin, arteriosclerosis, underdevelopment in children, multiplication of bacteria in the body, pyorrhea, gum

retraction, dental conditions, chronic conditions of the rectum, inflammation of the cervix, otitis media, otitis externa, Vincent's stomatitis, dry socket, common cold, ulcerative colitis, bacterial inflammation of the lining of the heart, digestive disorders, rheumatic pains and aches, illness, many sicknesses, deep-lying infections, hemiplegia, germ diseases, and acidosis. These statements, representations, and suggestions were false and misleading because not almost everyone is suffering from poor health resulting from a deficiency of minerals and vitamins caused by depleted soil and improper processing, storage, and cooking of foods; most diseases, ailments, and conditions which afflict mankind are not the result of malnutrition; and the articles, singly or in combination, would not be effective for the purposes mentioned.

Further misbranding, Section 502 (a), certain additional statements in the labeling of the articles were false and misleading. These statements represented and suggested that the use of the articles would be effective to stimulate the glands and liver, keep the muscles elastic, increase strength of the bones, protect the inside lining of the heart, blood vessels, and urinary passages, increase the bile function, act as a body purifier and cleanser, liven the skin, give pep and energy, enable one to enjoy life at its best, aid digestion, cleanse open wounds, enable the body to reach maximum health, assist the body to reach full health in a shorter space of time, raise the red blood cell count, build a healthy blood stream, invest the average person with far greater resistance against ordinary disease, conquer malnutrition and thereby prevent 95 percent of sickness, improve the health of every living man, woman, and child on the face of the earth, provide good health, supply a supplement needed by all persons not dead who eat present-day foods, give health, supply the body with all tools needed to reach good health, increase life expectancy and allow people to live a more full and happy life, prolong life, and effect better health and more vigor. The articles, singly or in combination, were not effective for the purposes stated and implied, and they would not fulfill the promises of benefit made for them.

DISPOSITION: April 30, 1951. Default decree of condemnation and destruction.

3477. Misbranding of Thorkon. U. S. v. 1,249 Packages, etc. (F. D. C. No. 29730. Sample No. 85549-K.)

LIBEL FILED: September 19, 1950, District of Minnesota; amended libel filed on January 17, 1951.

ALLEGED SHIPMENT: On or about August 4, 11, 16, 28, and 29, 1950, from Atlanta, Ga.

PRODUCT: 1,249 50-tablet packages of *Thorkon* at Minneapolis Minn., in possession of Snyder Drug Stores, Inc., together with a number of newspaper tear sheets entitled "Amazing Tablet Charges Blood," which sheets were printed locally from mats shipped from Atlanta, Ga.

LABEL, IN PART: (Package) "Thorkon A Nutritional Supplement Contents 50 Tablets Each Pink Tablet contains 5 micrograms Vitamin B₁₂.

Each Red Tablet contains:

Vitamin B ₁ (Thiamin Hydrochloride)	2.5	mos
Vitamin B ₆ (Pyridoxine Hydrochloride)	5	mg.
Calcium Pantothenate Dextro	1, 25	mgs.
Vitamin B ₂ (Riboflavin)		
Liver Fraction No. 2	1.0	gr.
Niacinamide	25.0	mgs.

Each White Tablet contains:

Iron (Iron Sulfate)	28.25	mg.
Calcium 93.5 mg. and Phosphorous 69.74 mg.		
(DiCalcium Phos.)		
Iodine (Potassium Iodide)	. 075	mg.
Magnesium (Magnesium Sulfate)	2.5	mg.
Sodium (Sodium Sulfate)		
Cobalt (Cobalt Sulfate)	0.1	mg.
Manganese (Manganese Sulfate)	1.7	mg.
Nickel (Nickel Sulfate)	. 56	mg.
Molybdenum (Molybdenum Trioxide)	1.0	mg.
Potassium (Potassium Sulfate)	. 67	mg."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying tear sheets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for all types of anemia, nervousness, weakness, underweight, poor appetite, dangerous infections, vague aches and pains, fatigue, poor digestion, and constipation; that it would be effective to insure the user pep, vigor, normal functioning of the stomach, heart, kidneys, liver, digestive and intestinal tracts, glands, brain, and other vital organs; that it would be effective to insure full health and full capacity to enjoy life and happiness; that it would be effective to enable one to obtain new strength and ambition, new endurance, strength, energy, muscle power, lustrous hair, calm, steady nerves, and clear, radiant skin; that it would be effective to restore to normal, people feeling half sick or half dead, run-down, depressed, leading a miserable, disappointing life, and held back and licked; and that it would be effective to prevent premature aging. The article was not effective for such purposes. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

Disposition: May 10, 1951. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution. On May 25, 1951, the decree was amended to provide for the destruction of the newspaper tear sheets.

3478. Misbranding of Surin ointment. U. S. v. 17 Jars, etc. (F. D. C. No. 30914. Sample Nos. 30771-L to 30774-L, incl.)

LIBEL FILED: April 12, 1951, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about October 18, November 27, and December 8 and 21, 1950, and February 28, 1951, from Bridgeport, Conn.

PRODUCT: 177 jars of Surin ointment at St. Louis, Mo., in possession of the Katz Drug Co.

RESULTS OF INVESTIGATION: There were on display in certain stores of the Katz Drug Co., together with jars of the article, one or more of the following pieces of written, printed, or graphic matter relating to the article, namely, arrows reading "Bursitis," "Sciatica," "Lumbago," "Arthritis," and "Rheumatism," and streamers entitled "Surin Kills Pain—Just Rub It On" and "Surin Kills Pain—No Internal Dosing." This material was prepared by the Katz Drug Co., Kansas City, Mo., and was distributed to their retail stores.

Label, In Part: (Jar) "Active Ingredients: Methacholine Chloride 0.25%, Camphor, Menthol, Methyl Salicylate, incorporated in a special white stainless water-soluble, greaseless base. Contents 1% Ounces."

Nature of Charge: Misbranding, Section 502 (a), certain statements appearing in the above-mentioned written, printed, and graphic matter relating to the product were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for bursitis, sciatica, lumbago, arthritis, and rheumatism, and that it would kill pain. The article was not an adequate and effective treatment for such conditions, and it would not kill pain. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 9, 1951. Default decree of condemnation and destruction.

3479. Misbranding of Bio-Radiation Therapy device. U. S. v. 1 Device * * *. (F. D. C. No. 30881. Sample No. 21040-L.)

LIBEL FILED: On or about April 4, 1951, Northern District of Texas.

ALLEGED SHIPMENT: On or about October 30, 1950, by Botanicals, Ltd., from Hollywood, Calif.

Product: 1 unlabeled *Bio-Radiation Therapy device* at Dallas, Tex., together with 1 5-page instruction leaflet entitled "Treating Manual for Bio-Radiation Therapy."

The device consisted of a polished metal plate, and a box, five sides of which were constructed of metal. The sixth or front side was closed with a layer of copper screen and several layers of colored cloth. A recess at each end, separated from the center of the box by a glass plate, held an electric light. The box contained a number of bags of herbs.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying instruction leaflet were false and misleading. The statements represented and suggested that the device was an adequate and effective treatment for asthma, anemia, constipation, colitis, cysts, carcinoma, diabetes, diarrhea, epilepsy, edema, ear infection, eye diseases, goiter, gangrene, gland disorders, high and low blood pressure, intestinal parasites (worms), leukemia, lymphatic diseases, menorrhagia, loss of memory, loss of voice, neuritis, nephritis, prostatitis, pneumonia, pains and burns, post operations, sinusitis, streptococcus infections, spider bites, skin diseases, tumors, tuberculosis, torticollis, ulcers, undulant fever, wounds, toxemia, acute conditions, chronic ailments, sarcomas, varicositis (sic), and deep-seated infections; that the device would put life into the body, rejuvenate age by the transfusion of youth, regenerate the cells and eventually raise the vitality to a level where an effective barrier to further pathology was effected, and give the body a higher immunity from colds, fever, and many ailments; and that the device would constitute a preventive therapy. The device was not an adequate and effective treatment for such diseases and conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: On or about June 5, 1951, a default decree of condemnation was entered and the court ordered that the device and the leaflet be delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

3480. Misbranding of mineral oil and isopropyl alcohol. U. S. v. 32 cases, etc. (F. D. C. No. 30717. Sample Nos. 31962-L, 31963-L, 31965-L, 31966-L.)

LIBEL FILED: On or about April 11, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about July 18 and September 24, 1950, and January 18, 1951, by the Roisman Products Co., from Oklahoma City, Okla.

PRODUCT: 32 cases, each containing 12 bottles, of *mineral oil* and 57 cases, each containing 12 bottles, of *isopropyl alcohol*, at Joplin, Mo.

Label, IN Part: "Step Brand Heavy Mineral Oil 1 Fl. Pint" and "Step Brand Isopropyl Alcohol Rubbing Compound One Fluid Pint."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles failed to bear labels containing an accurate statement of the quantity of the contents since the label designations "1 Fl. Pint" and "One Fluid Pint" were inaccurate. (The articles were short of the declared volume.)

DISPOSITION: May 31, 1951. Default decree. The court ordered that the products be delivered to a local hospital, to be used for charitable purposes.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3461 TO 3480

PRODUCTS

N. J. No.	N. J. No.
Acetyl-amino-benzaldehyde-thio-	Isopropyl alcohol 3480
semicarbazone 3461-3463	Massengill powder 3475
Adhesive bandages 3472	Mineral oil 3480
Alcohol, isopropyl 3480	Ointment, Surin 3478
Arthritis, remedy for 3474	Pentobarbital sodium capsules 3464
Bandages, adhesive 3472	Phenobarbital tablets 3466
Benzedrine Sulfate tablets 3465	Plantago husks 3468
Biogen products 3476	Premestrone (conjugated estro-
Bio-Radiation Therapy device 3479	gens) 3469
Braska tablets 3474	Pyorrhea, remedy for 3475
Carbrital capsules 3464	Seconal Sodium capsules 3464, 3465
Cedar leaf, oil of 3471	Surin ointment 3478
Devices 3467, 3473, 3479	TB-1. See Acetyl-amino-benzal-
Devine's Zina-Ray oil and De-	dehyde-thiosemicarbazone.
vine's inhaler 3467	Thermometers, clinical 3473
Estrogenic substances 3469, 3470	Thorkon 3477
Fleaseed (Plantago) husks 3468	Vitamin preparations 3476, 3477
Inhalers, Devine's, 3467	Zina-Ray oil, Devine's 3467

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N. J. No.	N. J. No.
Berje Chemical Products, Inc.:	Biogen Products Co.:
oil of cedar leaf 3471	Biogen products 3476

^{*}See also Nos. 3464-3466.

J. No.	N.	J. No.
	Massengill, S. E., Co.:	
3479	Massengill powder	3475
	Mealy, R. L.:	
	Seconal Sodium capsules and	
3463	Benzedrine Sulfate tablets	3465
	National Package Drugs, Inc.:	
	Braska tablets	3474
	Nutritional Industries, Inc.:	
3464	Biogen products	3476
	Persol Chemical Co.:	
	4-Acetylaminobenzaldehyde	
3467	Thiosemicarbazone (powder)	3462
	Renton Ten Cent Drug:	
	phenobarbital tablets	3466
3469	Retort Pharmaceutical Co., Inc.:	
	p-acetylaminobenzaldehyde	
	. thiosemicarbazone (powder)	3463
	Roisman Products Co.:	
3464	mineral oil and isopropyl alco-	
	hol	3480
	Snyder Drug Stores, Inc.:	
	Thorkon	3477
3473	Specific Bio-Chemicals:	
	Premestrone (conjugated es-	
3468	trogens)	3469
	Stearns, H. C., and I. S.:	
3478	Devine's Zina-Ray oil and De-	
	vine's inhaler	3467
	Supreme First Aid Co., Inc.:	
	adhesive bandages	3472
3461	Tuteur Bio-Chemicals, Inc.:	
- 0	estrogenic powder	3470
-		
	3463 3464 3467 3469 3464 3473 3468 3478	Massengill, S. E., Co.: Massengill powder



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

Course Trace 19250

32 Nd

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3481-3500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, Commissioner of Food and Drugs.

WASHINGTON, D. C., November 29, 1951.

CONTENTS *

1	Page		Page
New drugs shipped without effec-		Drugs and devices actionable be-	
tive application	472	cause of deviation from offi-	
Drugs and devices actionable be-		cial or own standards	477
cause of failure to bear ade-		Drugs and devices actionable be-	
quate directions or warning		cause of false and misleading	
statements	473	claims	479
Drugs for human use	473	Drugs for human use	479
Drug for veterinary use	476	Drugs for veterinary use	482

[•] For presence of a habit-forming narcotic without warning statement, see Nos. 3484-3486; omission of, or unsatisfactory, ingredients statements, Nos. 3484, 3485, 3487, 3497; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3484-3486; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3488; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3487.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3481. Misbranding of Histamist. U. S. v. 12 Cartons * * * (F. D. C. No. 30929. Sample No. 18772–L.)

LIBEL FILED: April 18, 1951, Southern District of Iowa.

ALLEGED SHIPMENT: On or about January 23, 1951, by the Histamist Corp., from Chicago, Ill.

Product: 12 display cartons, each containing 12 plastic bottles, of *Histamist* at Des Moines, Iowa. Examination showed that the article was a solution containing methapyrilene hydrochloride and desoxyephedrine hydrochloride.

Label, in Part: (Bottle) "Histamist An Antihistaminic and Decongestant nasal solution * * * * 13/4 fl. oz."

Nature of Charge: Misbranding, Section 502 (a), the following statements on the display carton of the article were false and misleading since the article was not an effective treatment for the conditions represented: "Histamist * * * for Head Colds - Sinus Misery * * * Helps resist infection * * * Check constant sore throats, infections, etc., from sinus drip Use Histamist for Direct relief * * * Do you have splitting sinus headaches? Smokers catarrh? Use Histamist for prompt relief * * * Do you have head colds, sinusitis * * * sinus headaches Use Histamist Check head cold and sinus misery in minutes Direct nasal sprays, for Direct relief."

Section 505 (a), the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

Disposition: May 24, 1951. Default decree of condemnation and destruction.

3482. TB-1 powder. U. S. v. 2 Drums * * * (F. D. C. No. 31157. Sample No. 24116-L.)

LIBEL FILED: May 29, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about May 14, 1951, A. E. Nydegger & Co., Inc., New York, N. Y., delivered the product for shipment from New York, N. Y., to Barcelona, Spain.

PRODUCT: 2 drums containing approximately 90 kilograms of *TB-1 powder* at New York, N. Y. Analysis showed that the product was para-acetyl-amino-benzaldehyde-thiosemicarbazone, commonly known as TB-1, a drug which has been used experimentally in the treatment of tuberculosis.

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: June 15, 1951. Default decree of condemnation and destruction.

3483. TB-1 tablets. U. S. v. 250 Bottles * * * (F. D. C. No. 30895. Sample No. 24520-L.)

LIBEL FILED: April 4, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 21, 1951, the Hudson Shipping Co., Inc., introduced the product into interstate commerce at Brooklyn, N. Y., for the account of Gallard-Schlesinger Chemical Co., New York, N. Y., for shipment to Portuguese West Africa.

PRODUCT: 250 1000-tablet bottles of TB-1 at Brooklyn, N. Y.

Label, IN Part: "TB1 (4 amino-acetyl-benzaldehyde thiosemicarbazone 50 mg. each) Gallard-Schlesinger Chemical Co., New York, N. Y."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: May 24, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

3484. Misbranding of Seconal Sodium tablets and Benzedrine Sulfate tablets. U. S. v. Abraham S. Brown (Cumberland Drug). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 30560. Sample Nos. 79942-K to 79946-K, incl., 79962-K to 79966-K, incl.)

Information Filed: June 1, 1951, District of Massachusetts, against Abraham S. Brown, trading as the Cumberland Drug, Boston, Mass.

ALLEGED SHIPMENT: From the States of Indiana and Pennsylvania into the State of Massachusetts, of quantities of Seconal Sodium tablets and Benzedrine Sulfate tablets.

ALLEGED VIOLATION: On or about June 15, 21, and 30, and July 7, 10, 14, 15, 19, 20, and 24, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One tablet at bedtime as needed" appearing in the labeling of the repackaged Seconal Sodium tablets and "One on arising ½ at noon," "as directed," and "One tablet on arising One tablet at noon" appearing in the labeling of the repackaged Benzedrine Sulfate tablets were not adequate directions for use; and, Section 502 (e) (1), the label of the repackaged Benzedrine Sulfate tablets failed to bear the common or usual name of the drug.

Further misbranding, Section 502 (d), the Seconal Sodium tablets contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designating as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Disposition: June 12, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$300.

3485. Misbranding of Benzedrine Sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules. U. S. v. Linus D. Drury Corp. (Drury's Pharmacy), and Ralph E. Anderson. Pleas of nolo contendere. Fine of \$250 against corporation and \$50 against individual. (F. D. C. No.

- 30583. Sample Nos. 79939–K, 79975–K to 79977–K, incl., 80311–K, 80365–K, 80371–K, 80441–K, 80541–K.)
- Information Filed: June 1, 1951, District of Massachusetts, against the Linus
 D. Drury Corp., trading as Drury's Pharmacy, Boston, Mass., and Ralph E.
 Anderson, treasurer of the corporation.
- INTERSTATE SHIPMENT: From the States of Pennsylvania, Illinois, and Indiana, into the State of Massachusetts, of quantities of Benzedrine Sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules.
- ALLEGED VIOLATION: On or about September 12, 14, 20, 22, 25, 27, and 28, and October 3 and 4, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One tablet at eight A. M. one at four P. M. with water" borne on the labeling of the Benzedrine Sulfate tablets and "One capsule at bedtime" borne on the labeling of the pentobarbital sodium capsules and the Seconal Sodium capsules were not adequate directions for use; and, Section 502 (e) (1), the repackaged Benzedrine Sulfate tablets failed to bear a label containing the common or usual name of the drug.

Further misbranding, Section 502 (d), the repackaged Seconal Sodium capsules and the pentobarbital sodium capsules contained derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

- DISPOSITION: June 12, 1951. Pleas of nolo contendere having been entered, the court fined the corporation \$250 and the individual \$50.
- 3486. Misbranding of phenobarbital tablets, Dexedrine Sulfate tablets, and thyroid tablets. U. S. v. Brice Carlton (Owl Drug Store), and Durward B. Allen. Pleas of nolo contendere. Imposition of sentence suspended and each defendant placed on probation for 1 year. (F. D. C. No. 30019. Sample Nos. 77127-K, 77713-K, 77717-K, 77728-K.)
- Information Filed: January 31, 1951, Western District of Arkansas, against Brice Carlton, trading as the Owl Drug Store, Nashville, Ark., and Durward B. Allen, an employee of Brice Carlton.
- INTERSTATE SHIPMENT: From the States of Indiana, Pennsylvania, and Tennessee, into the State of Arkansas, of quantities of phenobarbital tablets, Dexedrine Sulfate tablets, and thyroid tablets.
- ALLEGED VIOLATION: On or about March 8, 9, 15, and 16, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Brice Carlton was charged with causing the acts of repacking and sale of the drugs involved in each of the 4 counts of the information, and Durward B. Allen was charged likewise in 3 of the counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

- DISPOSITION: May 30, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence against the defendants and placed each defendant on probation for 1 year without supervision.
- 3487. Adulteration and misbranding of Crompton's headache powders. U. S. v. Charles Crompton & Sons, Inc., and George Crompton. Pleas of guilty. Fine of \$25 against each defendant. (F. D. C. No. 30003. Sample Nos. 63470-K, 63484-K, 63485-K.)
- INFORMATION FILED: January 12, 1951, District of Massachusetts, against Charles Crompton & Sons, Inc., Lynn, Mass., and George Crompton, president-treasurer of the corporation.
- ALLEGED SHIPMENT: On or about February 6 and April 5 and 8, 1950, from the State of Massachusetts into the State of Maine.
- Label, In Part: "Crompton's Headache Powders Each Dose Contains 2½
 Grains Acetanilid With Caffeine, Salol * * * Chas. Compton & Sons, Inc.
 Sole Proprietors Lynn, Massachusetts Contents: 9 Powders Of 1 Dose Each
 Nine 25¢ Size Powders."
- NATURE OF CHARGE: Adulteration, Section 501(c), the strength of the article differed from that which it was represented to possess since each dose of the article was represented to contain 2½ grains of acetanilid, whereas each dose of the article contained more than 2½ grains of acetanilid.

Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, and it was fabricated from 2 or more ingredients, one of which was acetanilid; and the label of the article failed to bear a statement of the quantity or proportion of the acetanilid contained therein. The label of the article bore the statement "Each Dose Contains 2½ Grains Acetanilid," whereas each dose of the article contained more than 2½ grains of acetanilid. Further misbranding, Section 502(c), the information required by Sections 502 (f) (1) and (2) to appear on the labeling was not prominently placed on the labeling with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the directions for use required by Section 502 (f) (1) to appear on the labeling and the warnings against use required by Section 502 (f) (2) to appear on the labeling were not legibly printed on the labeling of the article.

Disposition: May 23, 1951. Pleas of guilty having been entered, the court imposed a fine of \$25 against each defendant.

3488. Adulteration and misbranding of clinical thermometers. U. S. v. 54 Boxes, etc. (F. D. C. No. 31204. Sample No. 11388-L.)

LIBEL FILED: June 20, 1951, Northern District of Ohio.

Alleged Shipment: On or about February 12, 1951, by the Primus Thermometer Co., from New York, N. Y.

PRODUCT: 54 boxes and 54 envelopes each containing a stubby clinical thermometer at Cleveland, Ohio.

Examination of 15 thermometers showed that they failed to meet the requirements and tests specified in the United States Department of Commerce Commercial Standards for clinical thermometers since two failed to meet the entrapped gas test; two failed to meet the test for accuracy, and one of these failed also to meet the test for retreating index; and fourteen failed to meet the test for loss of pigment.

Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statement which appeared in the labeling of the article, namely, the "Certificate of Accuracy" which was enclosed in each box and envelope, was false and misleading as applied to a product which failed to meet the stated requirements and tests: "* * * Clinical Thermometer * * * carefully examined and tested and found to meet all of the requirements and tests specified in the United States Department of Commerce Commercial Standard for Clinical Thermometers."

Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling bore no directions for use.

Disposition: July 25, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3489. Misbranding of oil-acid-iodine. U. S. v. 22 Cases * * * . (F. D. C. No. 30909. Sample No. 25264–L.)

Libel Filed: On or about April 11, 1951, District of Delaware.

ALLEGED SHIPMENT: On or about December 19, 1950, by Hopkins & Hopkins Pharmaceutical Co., from Philadelphia, Pa. The product was invoiced by the M & D Sales Co., Snow Hill, Md.

PRODUCT: 22 cases, each containing 4 1-gallon bottles of oil-acid-iodine at Milton, Del. Examination showed that the product contained fish liver oil, hydrochloric acid, and iodine.

Label, in Part: (Bottle) "Oil-Acid-Iodine Treatment for Poultry Prof. C. E. Lee Formula."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the purpose for which the article was intended.

DISPOSITION: June 21, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

3490. Adulteration and misbranding of Testramone, Vitramone, A-Vee, and Harvaplex. U. S. v. Harvey Laboratories, Inc., and Frederick Greenbaum. Pleas of nole contendere. Corporation fined \$1,000 on count 1 and \$1,000 on count 2; sentence suspended on remaining counts. Individual fined \$100 on count 1 and placed on probation for 1 day on remaining counts. (F. D. C. No. 30013. Sample Nos. 12394-K, 73927-K to 73929-K, incl., 73931-K, 79342-K, 80876-K.)

Information Filed: January 9, 1951, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Frederick Greenbaum, secretary of the corporation.

ALLEGED SHIPMENT: On or about March 8 and 21 and April 5, 6, and 10, 1950, from the State of Pennsylvania into the States of New Jersey, Rhode Island, Delaware, and New York.

Label, IN Part: "Testramone [or "Harvaplex"] * * * Harvey Laboratories" and "Testramone [or "Vitramone" or "A-Vee"] * * * Dist. by Ardsley Labs. 999 Lexington Ave. N. Y. C."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the *Testramone* fell below that which it purported and was represented to possess since it purported and was represented to be suitable and appropriate for intramuscular injection, whereas it was not suitable and appropriate for such purpose since it was not sterile but was contaminated with viable micro-organisms; and the strength of the *Vitramone*, *A-Vee*, and *Harvaplex*, and a portion of the *Testramone*, differed from that which they purported and were represented to possess since they contained less than the labeled amount of riboflavin.

Misbranding, Section 502 (a), the statement "Intramuscular Injection" on the labels of the *Testramone* was false and misleading since the statement represented and suggested that the product would be suitable and appropriate for intramuscular injection, whereas it was not suitable and appropriate for such purpose since it was not sterile but was contaminated with viable micro-organisms; and the representations in the labeling of the *Vitramone* and *A-Vee* and a portion of the *Testramone* that each cubic centimeter of the products contained 2 milligrams of riboflavin and the representation in the labeling of the *Harvaplex* that each 2 cc. of the product contained 5 milligrams of riboflavin were false and misleading since the products contained less riboflavin than so represented.

DISPOSITION: March 28, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$1,000 on count 1 and \$1,000 on count 2 against the corporation and a fine of \$100 on count 1 against the individual defendant. The court suspended imposition of sentence on counts 3 to 14 with respect to the corporation and on counts 2 to 14 with respect to the individual defendant, and placed the individual on probation for 1 day.

^{*}See also Nos. 3487, 3488.

3491. Adulteration and misbranding of Conjugestoral tablets (conjugated estrogens). U. S. v. 2 Bottles * * *. (F. D. C. No. 30918. Sample No. 5010-L.)

LIBEL FILED: April 13, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 9 or 14, 1950, by the Corby-Franklin Associates, from New York, N. Y.

PRODUCT: 2 1,000-tablet bottles of *Conjugestoral tablets* (conjugated estrogens) at Boston, Mass. Analyses showed that the product contained a total amount of estrogenic steriods calculated to 0.34 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Tablets Conjugestoral (Conjugated Estrogens)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "1.25 mgm. of Estrogens in their naturally occurring water soluble conjugated form expressed as sodium estrone sulfate."

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the product, which contained less than the stated amount of estrogens.

DISPOSITION: May 21, 1951. Default decree of condemnation and destruction.

3492. Adulteration and misbranding of mephenesin. U. S. v. 4 Bottles * * *. (F. D. C. No. 31029. Sample No. 17260-L.)

LIBEL FILED: May 1, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about January 9, 1951, from Long Island City, N. Y., to Modern Medicals, Inc., Los Angeles, Calif.

Product: 4 1,000-capsule bottles of *mephenesin* at Los Angeles, Calif. After shipment in interstate commerce, Modern Medicals, Inc., repackaged the product in capsule form, relabeled it, and delivered the product to the person in whose possession it was at the time of seizure. Examination showed that the product contained an average of 0.166 grams of mephenesin per capsule.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Mephenesin 0.25 grams" was false and misleading as applied to an article which contained less than the stated amount of mephenesin per capsule.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 23, 1951. Default decree of condemnation and destruction.

3493. Adulteration and misbranding of sodium salicylate tablets. U. S. v. 1

Drum * * *. (F. D. C. No. 30892. Sample No. 25383-L.)

LIBEL FILED: April 4, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 12, 1951, by Morse Laboratories, Inc., from New York, N. Y.

PRODUCT: 1 drum containing 59,800 sodium salicylate tablets at Philadelphia, Pa. Analysis showed that the product contained not more than 93.5 percent of the labeled amount of sodium salicylate.

Label, in Part: (Drum) "Morse * * * Sodium Salicylate 5 Grains N. F."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The standard provides that sodium salicylate tablets contain not less than 95 percent of the labeled amount of sodium salicylate, whereas the article contained less than 95 percent of sodium salicylate.

Misbranding, Section 502 (a), the label designation "N. F." was false and misleading as applied to a product which was not official in the National Formulary.

Disposition: May 24, 1951. Default decree of condemnation and destruction.

3494. Adulteration and misbranding of prophylactics. U. S. v. 998 Gross

* * (F. D. C. No. 31022. Sample No. 10337-L.)

LIBEL FILED: April 24, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about March 7 and 29, 1951, by Central Sundries, Inc., from New York, N. Y.

PRODUCT: 998 gross of *prophylactics* at Pontiac, Mich. Examination of samples showed that 4.8 percent were defective in that they contained holes.

LABEL, IN PART: "Royal Knight Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Prophylactics" was false and misleading as applied to the article, because of the fact that it contained holes.

DISPOSITION: June 12, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3495. Misbranding of Bulgarian yogurt culture. U. S. v. 3 Cases * * *. (F. D. C. No. 30943. Sample No. 12887-L.)

LIBEL FILED: May 3, 1951, District of Colorado.

ALLEGED SHIPMENT: The drug was shipped on or about January 12, 1951, and a number of pamphlets on or about March 5, 1951, by the International Yogurt Co., from Los Angeles, Calif.

PRODUCT: 3 cases, each containing 12 1-ounce bottles, of Bulgarian yogurt culture at Denver, Colo., together with a number of accompanying pamphlets entitled "Yogurt." Examination of samples from other shipments of the product indicated that it was a culture of Lactobacilli.

^{*}See also Nos. 3481, 3488, 3490-3493.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying pamphlets were false and misleading. The statements represented and suggested that the article was effective to enable one to maintain or regain health; to improve vitality; to help in the digestion of other foods; to promote intestinal hygiene; to extend for years the period of one's usefulness; to prevent typhoid, paratyphoid, diphtheria, and numerous types of dysentery; and to synthetize the B vitamins; that it was effective as a dietary treatment of numerous digestive disorders, such as stomach and duodenal ulcers, flatulence, colitis, constipation, diarrhea and dysentery in infants, children, and adults; that it was effective to destroy pathogenic organisms; to improve health and prolong life, and to enable elderly persons to retain their vigor, mental alertness, attractiveness, appearance or glow of health, and other characteristics of youth; that it was effective to prevent illness, deafness, faulty eyesight, and any number of earmarks of physical degeneration in elderly people; and that it was effective in the treatment of mucous colitis and to insure a fine complexion. The article was not effective for the purposes represented.

DISPOSITION: June 18, 1951. The International Yogurt Co. having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the court ordered that the product be delivered to a charitable institution.

3496. Misbranding of Leal liniment. U. S. v. 16 Bottles, etc. (F. D. C. No. 30981. Sample No. 15087-L.)

LIBEL FILED: June 1, 1951, Southern District of Iowa.

ALLEGED SHIPMENT: On or about May 4, 1951, by the Leaf Oil Laboratories, from Sutton, Nebr.

Product: 16 3-ounce bottles and 12 6-ounce bottles of *Leal liniment* at Council Bluffs, Iowa. Analysis showed that the product consisted essentially of alcohol, water, and essential oils such as turpentine, cassia, and cloves.

LABEL, IN PART: "Leal Liniment 83% Alcohol."

Nature of Charge: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in a circular entitled "Leal Liniment," which was attached to each bottle with a rubber band, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for bumps, bruises, sprained ankle or side, crushed muscles, pain caused by weather changes, headache, head colds, stiff neck, sore and tender lips, frosted hands, sinusitis, rheumatism, arthritis, varicose veins, hemorrhoids or piles, corns, bunions, and conditions where irritation, inflammation, fever, or congestion exist; that the article would penetrate deeply and prevent existence of poison germs and irritating substances; and that it was the nearest approach to a cure-all. The article was not an adequate and effective treatment for the conditions represented; it would not penetrate deeply and prevent existence of poison germs and irritating substances; and it was not the nearest approach to a cure-all.

DISPOSITION: June 29, 1951. Default decree of condemnation and destruction.

3497. Misbranding of Bob's Gypsy Rub liniment. U. S. v. 12 Bottles, etc. (F. D. C. No. 30912. Sample Nos. 12771-L, 12772-L.)

LIBEL FILED: April 17, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about June 13, 1950, by the C. G. Smith Products Co., from Blytheville, Ark.

Product: Bob's Gypsy Rub liniment. 12 6-ounce bottles, 8 2-ounce bottles, 12 1-pint bottles, and 12 1-quart bottles at Denver, Colo., together with a number of booklets entitled "Bob's Gypsy Rub No. 1."

Analysis showed that the product consisted essentially of wintergreen, menthol, ether, and belladonna alkaloids.

Label, IN Part: "Bob's Gypsy Rub Liniment * * * Contains: Menthol, Oil of Wintergreen, Oil of Eucalyptus, Tincture of Belladonna, Camphorated Oil, and Ether."

Nature of Charge: Misbranding, Section 502 (a), certain statements on the labels of the article and in the booklet were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for common colds, neuritis, arthritis, rheumatism, stiff or painful joints or muscles, asthma, headaches, lumbago, tonsillitis, sinusitis, osteomyelitis, bruised bones, corns and bunions of humans, ruptured tendons, curbs, bone spavins, splints, sore shoulders, quarter cracks, ossicle trouble, sesamoid trouble, suspensory trouble, shipping colds, pneumonia, kidney trouble, sore ligaments, sore joints, stiff joints, sore legs, soreness of all kinds, shipping soreness, lameness, sickness, bad legs, all swellings, cuts, colds, threatening pneumonia, and capped hocks of horses; that the article would keep horses in good working condition; that it would prevent colds in horses; that it would perform a miracle; and that it would remove scar tissue. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit made for it.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the quantity of ether and belladonna alkaloids contained therein.

Disposition: June 4, 1951. The C. G. Smith Products Co. having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3498. Misbranding of Inducto-Scope. U. S. v. 18 Devices * * * (F. D. C. No. 31146. Sample No. 11423-L.)

LIBEL FILED May 21, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 10 and April 1, 17, and 26, 1951, by the Macy Co., from St. Petersburg, Fla.

PRODUCT: 18 Inducto-Scopes at Parma, Ohio, together with a number of copies of a booklet entitled "Inducto-Scope."

The device consisted of 2 coils about 10 inches in diameter, covered with a woolen material, and each coil containing approximately 500 turns of wire.

Attached to one coil was a cord equipped with a plug to fit into a wall receptacle. The coils were connected with an insulated cord bearing a switch. With the current on, the device would produce a moderately weak alternating magnetic field.

Nature of Charge: Misbranding, Section 502 (a), certain statements in the booklet were false and misleading. The statements represented and suggested that the device was a factor in restoring and preserving health; that it would combat disease, energize body tissues by increasing the activity of the cells and thereby normalizing metabolic processes, and give new energy and pep; and that the device was effective in the relief of arthritis, neuritis, eyeritis [sic], rheumatism, neuralgia, sciatica, lumbago, inflammatory joints, asthma, nasal catarrh, colds, sinusitis, impaired eyesight, earache, migraine headache, tonsillitis bronchitis, pleurisy, intestinal catarrh, constipation, catarrh of kidney and bladder, kidney trouble, prostate trouble, ovary congestion, female weakness, varicose veins, respiratory conditions, conditions caused by congested circulation, and every ache and pain. The device was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: June 28, 1951. Default decree of condemnation and destruction. On August 16, 1951, an amendment to the decree was entered, ordering that the devices be released to the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

3499. Misbranding of Sulfa-Du. U. S. v. 25 Jugs * * *. (F. D. C. No. 31151. Sample No. 31569–L.)

LIBEL FILED: May 21, 1951, Western District of Arkansas.

ALLEGED SHIPMENT: On or about April 11, and 27, 1951, by the Hill Poultry Service, from Dallas, Tex.

PRODUCT: 25 1-gallon jugs of Sulfa-Du at Springdale, Ark.

Label, IN Part: "Chemic Brand Farm Chemistry Associates Sulfa-Du

* * Each 100 cc contains an equal of 4.5 grams of Sulfathiazole."

NATURE of CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not an effective treatment of infectious coryza in poultry, as represented: "For Infectious Coryza (Colds) In Poultry * * * When symptoms of Infectious Coryza appear in a flock, add two ounces of Sulfa-Du to all drinking water for 24 hours, then add one ounce per gallon for next two days. Allow only medicated water during treatment. If birds do not respond to treatment * * * have diagnosis re-established."

DISPOSITION. June 26, 1951. Default decree of condemnation and destruction.

3500. Misbranding of Viking saturation feed. U. S. v. 18 Drums * * *. (F. D. C. No. 31176. Sample No. 30030-L.)

LIBEL FILED: June 18, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about April 23, 1951, by Viking Laboratories, Inc., from Des Moines, Iowa.

Product: 18 25-pound drums of Viking saturation feed at Seattle, Wash., together with a number of circulars entitled "Viking Vilak" and "The Roundup."

^{*}See also No. 3497.

Label, in Part: (Drum) "Viking Saturation Feed * * * Guaranteed Analysis—

Protein	not less than	18.5%
Fat	not less than	5.0%
Fibre	not less than	3.5%
Calcium	not less than	4.0%
Phos. (P)	not less than	1.8%
Iodine (I)	not less than	. 0046%
Salt		none

Ingredients Wheat Germ, Wheat Germ Oil, Wheat Gray Shorts, Di-calcium Phosphate, Fish Solubles, Soybean Meal, Dried Whey, Manganese Sulphate, Potassium Iodide, Copper Sulphate, Cobalt Carbonate, Zinc Sulphate, Ferrous Sulphate, Soft Phosphate with Colloidal Clay. * * * A compound for special feeding to correct breeding failures when due to a deficiency of Vitamin E, Riboflavin and Trace Minerals. To Help Settle Sows * * * feed only before breeding. To Help Save Little Pigs * * * Boars * * * feed before putting boar in service. To Help Settle Cows * * * To Help Settle Ewes * * * Feed the buck * * * before putting in service."

(Circular entitled "Viking Vilak") "To overcome Vitamin E' deficiencies Deficiencies of Vitamin E often show up in breeding failures in brood sows." (Circular entitled "The Roundup") "Failure of sows to breed and farrowing of dead litters is in a large percentage of cases due to low reserves of Vitamin E in the livers of the saw. When activated by Copper Manganese.

Vitamin E in the livers of the sow. When activated by Copper, Manganese, and Iron, this Vitamin deficiency can be taken care of by a single massive dose of material rich in Vitamin E."

NATURE of CHARGE: Misbranding, Section 502 (a), the statements on the drum label and in the circulars were false and misleading since the article was not capable of fulfilling the promises of benefit made for it.

Disposition: July 18, 1951. Viking Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3481 TO 3500

PRODUCTS

N. J. No.		N. J. No.
A-Vee	3490	Estrogenic substances 3490, 3491
Acetyl-amino-benzaldehyde-thio-		Harvaplex 3490
semicarbazone powder	3482	Headache powders, Crompton's 3487
tablets	3483	Histamist 3481
Androgenic substances	3490	Inducto-Scope 3498
Antihistaminic nasal spray	3481	Leal liniment 3496
Benzedrine Sulfate tablets 3484	, 3485	Liniment 3496, 3497
Bob's Gypsy Rub liniment	3497	Mephenesin capsules 3492
Bulgarian yogurt culture	3495	Nasal spray, antihistaminic 3481
Clinical thermometers	3488	Oil-acid-iodine 3489
Conjugestoral tablets	3491	Parenteral drugs, contaminated_ 3490
Crompton's headache powders	3487	Pentobarbital sodium capsules 3485
Devices 3488, 3494,	3498	Phenobarbital tablets 3486
Dexedrine Sulfate tablets	3486	Prophylactics 3494

	. J. No.		J. No.
Seconal Sodium capsules	3485	Thyroid tablets	
tablets	3484	Veterinary preparations	
Sodium salicylate tablets		3497, 349	
Sulfa-Du	3499	Viking saturation feed	3500
TB-1. See Acetyl-amino-benzal-		Vitamin preparations	
dehyde-thiosemicarbazone.	0.400	Vitramone	
Testramone	3490	Yogurt culture, Bulgarian	3495
Thermometers, clinical	3488		
SHIPPERS, MANUF	ACTUE	EERS, AND DISTRIBUTORS	
	. J. No.		
Allen, D. B.:	. J. 140.	Greenbaum, Frederick:	. J. No.
phenobarbital tablets, Dex-	_	Testramone, Vitramone, A-Vee,	
edrine Sulfate tablets, and		and Harvaplex	9400
thyroid tablets	3486	Harvey Laboratories, Inc.:	3490
Anderson, R. E.:	0100	Testramone, Vitramone, A-Vee,	
Benzedrine Sulfate tablets,		and Harvaplex	9400
pentobarbital sodium cap-		Hill Poultry Service:	3490
sules, and Seconal Sodium		Sulfa-Du	9.400
capsules	3485	Histamist Corp.:	3499
Ardsley Labs.:		Histamist Corp.:	0.404
Testramone, Vitramone, and		Hopkins & Hopkins Pharma-	3481
A-Vee	3490	ceutical Co.:	
Brown, A. S.:			0.400
Seconal Sodium tablets and		oil-acid-iodine	3489
Benzedrine Sulfate tablets	3484	Hudson Shipping Co., Inc.:	
Carlton, Brice:		TB-1 tablets	3483
phenobarbital tablets, Dex-		International Yogurt Co.:	
edrine Sulfate tablets, and		Bulgarian Yogurt culture	3495
thyroid tablets	3486	Leaf Oil Laboratories:	
Central Sundries, Inc.:		Leal liniment	3496
prophylactics	3494	M & D Sales Co.:	
Corby-Franklin Associates:		oil-acid-iodine	3489
Conjugestoral tablets (conju-		Macy Co.:	
gated estrogens)	3491	Inducto-Scope	3498
Crompton, George:		Modern Medicals, Inc.:	
Crompton's headache powders_	3487	mephenesin	3492
Crompton, Charles, & Sons, Inc.:	0.40-	Morse Laboratories, Inc.:	
Crompton's headache powders_	3487	sodium salicylate tablets	3493
Cumberland Drug. See Brown,	- 10	Nydegger, A. E., & Co., Inc.:	
A. S.		TB-1 powder	3482
Drury, Linus D., Corp.: Benzedrine Sulfate tablets.		Owl Drug Store. See Carlton,	
Benzedrine Sulfate tablets, pentobarbital sodium cap-		Brice.	
sules, and Seconal Sodium	- 4	Primus Thermometer Co.:	
capsules	3485	clinical thermometers	3488
Drury's Pharmacy. See Drury,	9100	Smith, C. G., Products Co.:	
Linus D., Corp.		Bob's Gypsy Rub liniment	3497
Gallard-Schlesinger Chemical Co.:		Viking Laboratories, Inc.:	
TB-1 tablets	3483	Viking saturation feed	3500
		U. S. GOVERNMENT PRINTING OFFICE: 1951	
		U. S. GOVERNMENT PRINTING OFFICE: 1951	



The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3501-3520

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

Charles W. Crawford, Commissioner of Food and Drugs. Washington, D. C., December 19, 1951.

CONTENTS *

Pag	ge	P	age
New drugs shipped without effective application	2	Drugs and devices actionable be-	
Drugs and devices actionable be-		or own standards	6
cause of failure to bear adequate directions or warning		Drugs actionable because of false and misleading claims	11
statements	2	Index	12
Drugs for human use	2		
Drug for veterinary use	5		

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3503, 3504; omission of, or unsatisfactory, ingredients statements, No. 3504; failure to bear a label containing an accurate statement of the quantity of the contents, No. 3504.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3501. TB-1-PSL tablets. U. S. v. 97 Bottles, etc. (F. D. C. No. 30310. Sample No. 35715-K.)

LIBEL FILED: December 8, 1950, Northern District of California.

ALLEGED SHIPMENT: On or about November 8, 1950, U. S. Factors, San Francisco, Calif., acting for Pacific States Laboratories, Inc., San Francisco, Calif., delivered the product for shipment to Bangkok, Thailand.

PRODUCT: 97 100-tablet bottles and 497 12-tablet bottles of TB-I-PSI, at San Francisco, Calif., together with a number of leaflets entitled "Reference Manual 601 TB1-PSL The New Antituberculous Drug."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3502. Tetraethylthiuram disulfide. U. S. v. 1 Drum * * * (F. D. C. No. 30915. Sample No. 22825-L.)

LIBEL FILED: April 13, 1951, Eastern District of New York.

ALLEGED SHIPMENT: Prior to April 13, 1951, the Red Star Chemical Co., Inc., introduced the drug into interstate commerce at Long Island City, N. Y., for shipment to Santiago, Chile, in response to an order dated February 26, 1951.

PRODUCT: I drum containing 10 kilograms of tetraethylthiuram disulfide at Long Island City, N. Y.

Label, in Part: "Tetraethylthiuram Disulfide New Drug—For Experimental Purposes Only."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: June 22, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

3503. Adulteration and misbranding of amphetamine sulfate dextrorotatory tablets, amphetamine phosphate dextrorotatory tablets, rutin and ascorbic acid tablets, ascorbic acid tablets, and sulfamerazine tablets, and misbranding of stilbestrol tablets and elixir of phenobarbital. U. S. v. Hopkins & Hopkins Pharmaceutical Co. and Michael P. Hopkins. Pleas of guilty. Fine of \$1,200 against company. Sentence of 1 day in jail against individual suspended; individual placed on probation for 1 day. (F. D. C. No. 30590. Sample Nos. 34820-K to 34822-K, incl., 63510-K to 63512-K, incl., 76150-K.)

Information Filed: June 6, 1951, Eastern District of Pennsylvania, against the Hopkins & Hopkins Pharmaceutical Co., a corporation, Philadelphia, Pa., and Michael P. Hopkins, president of the corporation.

ALLEGED SHIPMENT: On or about May 15 and 23 and June 22, 1950, from the State of Pennsylvania into the States of California, Maine, and Iowa.

NATURE OF CHARGE: Amphetamine sulfate dextrorotatory tablets and ampheta-

mine phosphate dextrorotatory tablets. Adulteration, Section 501 (d) (2), amphetamine racemic or a salt of amphetamine racemic had been substituted for amphetamine sulfate dextrorotatory and amphetamine phosphate dextrorotatory, which the respective drugs were represented to be. Misbranding, Section 502 (a), the label designations "Amphetamine Sulphate Dextro Rotatory" and "Amphetamine Phosphate Dextro Rotatory" were false and misleading since the drugs were amphetamine racemic or a salt of amphetamine racemic.

Rutin and ascorbic acid tablets. Adulteration, Section 501 (c), the strength of the tablets differed from that which they were represented to possess since they were represented to contain 100 milligrams of ascorbic acid in each tablet, whereas the tablets contained less than 100 milligrams of ascorbic acid in each tablet. Misbranding, Section 502 (a), the label statement "Ascorbic Acid 100 mg." was false and misleading.

Sulfamerazine tablets. Adulteration, Section 501 (b), the article was represented to be a drug the name of which, "Sulfamerazine Tablets," is recognized in the United States Pharmacopeia, an official compendium; and its strength differed from the official standard since the article contained less than 95 percent of the labeled amount of sulfamerazine, the minimum permitted by the standard, and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Sulfamerazine Tablets 7.7 gr." was false and misleading since the article contained less than 7.7 gr. of sulfamerazine.

Ascorbic acid tablets. Adulteration, Section 501 (b), the article was represented to be a drug the name of which, "Tablets Ascorbic Acid," is recognized in the United States Pharmacopeia, an official compendium; and its strength differed from the official standard since the article contained less than 95 percent of the labeled amount of ascorbic acid, the minimum permitted by the standard, and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Tablets Ascorbic Acid 100 mg." was false and misleading since each tablet of the article contained less than 100 milligrams of ascorbic acid.

Stilbestrol tablets. Misbranding, Section 502 (f) (1), the labeling of the article bore no directions for use; and, Section 502 (f) (2), the labeling of the article bore no warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Elixir of phenobarbital. Misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the proportion of such derivative contained in the article and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the article bore no directions for use.

Disposition: June 21, 1951. Pleas of guilty having been entered, the court imposed a fine of \$1,200 against the company and a sentence of 1 day in jail against the individual defendant. The jail sentence against the individual was suspended, and he was placed on probation for 1 day.

3504. Misbranding of Donnatal tablets, Benzedrine Sulfate tablets, Tuinal capsules, and Dexedrine Sulfate tablets. U. S. v. Wiles Drug Store, a partnership, and Clyde B. Wiles and W. Paul Wiles. Pleas of nolo con-

tendere. Fine of \$750 against Clyde B. Wiles and partnership on 4 counts of information; fine of \$750 against W. Paul Wiles and partnership on remaining 4 counts of information. (F. D. C. No. 30607. Sample Nos. 76805–K, 76817–K, 76824–K, 76825–K, 76829–K, 76830–K, 76833–K.)

Information Filed: July 6, 1951, Western District of Tennessee, against the Wiles Drug Store, a partnership, Memphis, Tenn., and against Clyde B. Wiles and W. Paul Wiles, partners in the partnership.

Interstate Shipment: From the States of Virginia, Indiana, and Pennsylvania, into the State of Tennessee, of quantities of Donnatal tablets, Benzedrine Sulfate tablets, Tuinal capsules, and Dexedrine Sulfate tablets.

ALLEGED VIOLATION: On or about August 4 and 27, and September 18, 24, and 28, 1950, while the drugs were being held for sale at the Wiles Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Wiles Drug Store was charged in each of the 8 counts of the information, Clyde B. Wiles in 4 counts, and W. Paul Wiles in the remaining 4 counts, with causing the acts of repacking and sale of the drugs involved in those counts.

Nature of Charge: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One three times a day" borne on the labeling of the *Donnatal tablets*, "One-half tablet one hour before meals" borne on the labeling of the *Benzedrine Sulfate tablets*, "One at bedtime" borne on the labeling of the *Tuinal capsules*, and "One twice a day" borne on the labeling of the *Dexedrine Sulfate tablets* were not adequate directions for use.

Further misbranding, Section 502 (d), the *Donnatal tablets* and the *Tuinal capsules* contained derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the *Benzedrine Sulfate tablets* and the *Dexedrine Sulfate tablets* failed to bear labels containing the common or usual name of such drugs; and, Section 502 (e) (2), the repackaged *Donnatal tablets* contained hyoscyamine sulfate, hyoscine hydrobromide, and atropine sulfate, and the label of such repackaged tablets failed to bear the name, and quantity or proportion of such substances.

DISPOSITION: July 12, 1951. Pleas of nolo contendere having been entered, the court fined Clyde B. Wiles and the partnership \$750 on 4 counts of the information and W. Paul Wiles and the partnership \$750 on the remaining 4 counts of the information.

3505. Misbranding of Violetta kits. U. S. v. 21 Kits, etc. (F. D. C. No. 30942. Sample No. 25412-L.)

LIBEL FILED: May 3, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, May 8, November 11 and 17, and December 9, 1950, and March 10 and 15, 1951, by Electro-Technic Products, from Chicago, Ill.

PRODUCT: 21 brown simulated leather No. 411 Violetta kits, each kit containing a Violetta generator, to which was attached an electric cord; a No. 1 or "General" electrode; and a leaflet entitled "Warning." In addition to the above kits, there were 35 unlabeled accessory attachments consisting of electrodes of various shapes and a number of leaflets entitled "The Advanced Violetta Kits" and "Violetta Electrodes," at Philadelphia, Pa.

The device was an electrical generator to be plugged into an electric outlet to produce a high voltage, higher frequency electrical current. The various shaped electrodes were to be used interchangeably on the generator, and consisted of hermetically sealed glass tubes, each containing a gas under low pressure.

Nature of Charge: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to specify the method of using the device in the treatment of conditions of the prostate, ear, spine, inside of the throat, vagina, nasal passages, urethra, rectum, and dental abscesses, and for the removal of moles, warts, and growths, which were the purposes and conditions for which the device was offered in the leaflet entitled "Violetta Electrodes" accompanying the device.

Further misbranding, Section 502 (a), the following statements in the accompanying leaflets entitled "The Advanced Violetta Kits" and "Violetta Electrodes" were false and misleading since the device was not capable of producing the effects claimed or of providing benefit in all conditions of the various organs of the body stated and implied: (Leaflet entitled "The Advanced Violetta Kits") " * * * electrical aid in treatments of the skin or the scalp * * * ," " * * * provide the therapeutic values desired to aid in the correction of skin and scalp deficiencies," "It brings nourishment to the hair follicles if used as a scalp treatment or, if used for general body or facial work, the stimulating qualities of the rays carry the food values in the blood stream to feed the epidermis cells on the surface of the body," and " * * * for the treatment of many common conditions"; and (leaflet entitled "Violetta Electrodes") " * * * for any surface application," " * * * very desirable in deep-seated cases," "Used for all scalp treatments. Stimulates the hair roots and cells," "For spinal treatments," "Throat Electrode," "Special Vaginal Electrode," "Vaginal Electrode," "Prostatic Electrode," "Length just right to reach prostate gland," "Internal Throat Electrode," "Nasal and Ear Electrode," "A special Ear Elec-* * * fits in the ear passage," "Urethral Electrode," "Rectual Electrode," "Dental Electrode," and "Dental Abscess."

DISPOSITION: June 27, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3506. Misbranding of oil-acid-iodine. U. S. v. 29 Cases * * * (F. D. C. No. 30908. Sample No. 25263-L.)

LIBEL FILED: On or about April 11, 1951, District of Delaware.

ALLEGED SHIPMENT: On or about March 2, 1951, by Whitmoyer Laboratories, Inc., from Myerstown, Pa.

Product: 29 cases, each containing 4 1-gallon bottles, of oil-acid-iodine at

Milton, Del. Examination showed that the product contained fish liver oil, hydrochloric acid, and iodine.

Label, In Part: (Bottle) "Oil-Acid-Iodine Treatment for Poultry In accordance with formula of Prof. C. E. Lee."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the purpose or purposes for which the article was intended.

DISPOSITION: June 21, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

3507. Adulteration of dl-amphetamine sulfate (powder). U. S. v. 1 Drum

* * * . (F. D. C. No. 30888. Sample Nos. 22871–L, 22873–L.)

LIBEL FILED: April 3, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about January 18, 1951, by the Arenol Chemical Corp., from Long Island City, N. Y.

PRODUCT: 1 drum containing 5½ pounds of dl-amphetamine sulfate (powder) at East Newark, N. J.

Nature of Charge: Adulteration, Section 501 (b), the article purported to be and was represented as "dl-amphetamine sulfate," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The compendium requires that dl-amphetamine sulfate contain equal molecular proportions of dextro-amphetamine sulfate and levo-amphetamine sulfate, whereas the article contained approximately 42 percent of the former and 58 percent of the latter.

DISPOSITION: July 11, 1951. Default decree of condemnation and destruction.

3508. Adulteration and misbranding of tincture of belladonna. U. S. v. 4
Bottles * * *. (F. D. C. No. 31190. Sample No. 4843-L.)

LIBEL FILED: June 11, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 26, 1951, by Standard Drug Co., Inc., from Newark, N. J.

PRODUCT: 4 1-gallon bottles of tincture of belladonna at Worcester, Mass. Analysis showed that the article yielded from each 100 cc. not more than 16.3 mg. of the alkaloids of belladonna leaf.

Label, in Part: "Quality Purity Standard Tincture of Belladonna U.S.P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Belladonna Tincture," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since the article yielded from each 100 cc. less than 27 mg. of the alkaloids of belladonna leaf, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label designation "Tincture of Belladonna U. S. P." was false and misleading as applied to an article which was not Tincture of Belladonna U. S. P.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

^{*}See also No. 3503.

3509. Adulteration of diphenylhydantoin sodium capsules. U. S. v. 1 Can * * *. (F. D. C. No. 30939. Sample No. 5164-L.)

LIBER FILED: On or about May 3, 1951, District of Rhode Island.

ALLEGED SHIPMENT: On or about March 2, 1951, by the Richlyn Laboratories, from Philadelphia, Pa.

PRODUCT: 1 can containing 18,000 capsules of diphenylhydantoin sodium at Howard, R. I.

Label, in Part: "Diphenyl Hydantoin Sodium 11/2 Grains."

NATURE of CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Diphenylhydantoin Sodium Capsules," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium. The compendium provides that diphenylhydantoin sodium capsules contain not less than 93 percent of the labeled amount of diphenylhydantoin sodium, whereas the article contained not more than 86 percent of the labeled amount of diphenylhydantoin sodium.

DISPOSITION: June 21, 1951. Default decree of condemnation and destruction.

3510. Adulteration and misbranding of conjugated estrogens. U. S. v. 1

Bottle * * * . (F. D. C. No. 31315. Sample No. 24522-L.)

Libel Filed: July 3, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about December 21, 1950, from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle of conjugated estrogens at Bayonne, N. J. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.66 mg. of sodium estrone sulfate per tablet.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained in each tablet less than the stated amount of the total estrogenic steroids calculated as sodium estrone sulfate.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: August 14, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Federal Security Agency.

3511. Adulteration and misbranding of Cogenat tablets (conjugated estrogens).
U. S. v. 195 Bottles, etc. (F. D. C. No. 31231. Sample Nos. 1831-L, 1832-L.)

LIBEL FILED: On or about July 5, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about June 30 and July 8 and 19, 1949, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: Cogenat tablets (conjugated estrogens). 195 100-tablet bottles, 1 1,000-tablet bottle, and 19 100-tablet bottles at Atlanta, Ga.

Analysis showed that the 195-bottle lot contained a total amount of estrogenic steroids calculated as not more than 0.38 mg. of sodium estrone sulfate per tablet, and that the 1-bottle and the 19-bottle lots contained a total amount

of estrogenic steroids calculated as not more than $0.55~\mathrm{mg}$. of sodium estrone sulfate per tablet.

LABEL, IN PART: (195-bottle lot) "Cogenat 0.625 mg. Conjugated Estrogens" and (1-bottle and 19-bottle lots) "Cogenat 1.25 mg. Conjugated Estrogens."

NATURE of CHARGE: Adulteration, Section 501 (c), the strength of the article in each of the two lots differed from that which it was represented to possess, namely, 0.625 mg. and 1.25 mg., respectively, of conjugated estrogens expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statements on the two lots of the article, namely, "Each tablet contains: Conjugated Estrogens * * * 0.625 mg. [or "1.25 mg."] expressed as Sodium Estrone Sulfate" were false and misleading as applied to an article containing less than the stated amounts of estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3512. Adulteration and misbranding of Conjugens tablets and Conjugestoral tablets (conjugated estrogens). U. S. v. 2 Bottles, etc. (and 1 other seizure action). (F. D. C. Nos. 30767, 39872. Sample Nos. 23103-L, 23105-L.)

LIBELS FILED: March 8 and 27, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about November 20 and 22 and December 4, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 2 1,000-tablet bottles and 1 bottle containing 600 tablets of *Conjugens* and 1 1,000-tablet bottle of *Conjugestoral* at East Orange, N. J., and 1 bottle containing approximately 350 *Conjugens* tablets at Bloomfield, N. J.

Analyses of two samples taken from the shipments of *Conjugens* showed the total amount of estrogens actually present in the samples to be equivalent to 0.56 mg. and 0.78 mg., respectively, of sodium estrone sulfate per tablet. Analysis of a sample of the *Conjugestoral* tablets showed the total amount of estrogens actually present in the sample to be equivalent to 0.35 mg. of sodium estrone sulfate per tablet.

Label, in Part: "Tablets Conjugens (Conjugated Estrogens) * * * Distributed by Success Chemical Co., Inc., Brooklyn, New York" and "Tablets Conjugestoral (Conjugated Estrogens) * * * Distributors Corby-Franklin Associates New York, N. Y."

NATURE of CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mgm. of Estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to the articles, which contained less than the stated amount of estrogens.

DISPOSITION: July 11 and 12, 1951. Default decrees of condemnation. The court ordered that the lot seized at Bloomfield be destroyed and that the lots seized at East Orange be delivered to the Food and Drug Administration.

3513. Adulteration and misbranding of Estrotron. U. S. v. 40 Bottles * * *. (F. D. C. No. 30930. Sample No. 29728-L.)

LIBEL FILED: April 24, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about January 2, February 2, and March 9, 1951, by the Pitman-Moore Co., from Indianapolis, Ind.

PRODUCT: 40 bottles of *Estrotron* at Seattle, Wash. Examination showed that the product contained not more than 1.18 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * Estrotron, 2 mg. (20,000 I. U.) per cc. in Peanut Oil. A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle and carton label) "* * Estrotron, 2 mg. (20,000 I. U.) per cc. * * * consisting primarily of estrone with smaller quantities of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * * " and (accompanying leaflet entitled "Estrotron") " * * * containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: June 18, 1951. Default decree of condemnation and destruction.

3514. Adulteration and misbranding of Premestrone (conjugated estrogens).

U. S. v. 197 Bottles * * *, (F. D. C. No. 30734. Sample No. 10119-L.)

LIBEL FILED: April 9, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 9, 1951, by the Doctors' Mutual Service Co., from Glendale, Calif.

PRODUCT: 197 bottles of *Premestrone* (conjugated estrogens) at Detroit, Mich. Examination showed that the total amount of estrogens actually present in the article was equivalent to 0.22 mg. of sodium estrone sulfate per tablet.

Label, IN Part: "Premestrone 0.4 mg. 90 Tablets Estrogenic Substances (Water Soluble). Also Known As Conjugated Estrogens (Equine). * * * Formulated And Distributed By Specific Bio-Chemicals Glendale, California."

Nature of Charge: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 0.4 mg. of estrogens in their water-soluble form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 0.4 mg. of estrogens in their water soluble form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained 0.22 milligram of sodium estrone sulfate per tablet.

DISPOSITION: June 12, 1951. Default decree of condemnation and destruction.

3515. Adulteration and misbranding of Hemotene tablets. U. S. v. 148 Bottles, etc. (F. D. C. No. 31181. Sample No. 16763-L.)

Libel Filed: June 7, 1951, Southern District of California; amended libel filed June 28, 1951.

ALLEGED SHIPMENT: On or about December 30, 1950, and March 2, 1951, by the Midwest Chemical Development Corp., from Cleveland, Ohio.

PRODUCT: Hemotene tablets. 148 bottles, each containing 270 tablets, and 443 bottles, each containing 90 tablets, at Los Angeles, Calif. Analysis showed that the article contained substantially less than the stated amount of vitamins C and D.

LABEL, IN PART: (Bottle) "Hemotene With Organic Iron and B-12."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 120 milligrams of vitamin C and 2,000 U. S. P. units of vitamin D.

Misbranding, Section 502 (a), the label statements "Six Hemotene Tablets provide: * * * Vitamin C 120 milligrams Vitamin D 2000 U. S. P. Units * * * Six tablets supply * * * M. D. R. * * * 4 times that of Vitamin C and 5 times that of Vitamin D" were false and misleading as applied to an article containing less than the stated amounts of vitamins C and D. Further misbranding, Section 502 (a), the label designation "Hemotene With Organic Iron and B-12" was false and misleading. The label designation represented and suggested that the article, because of its vitamin B₁₂ content, was effective in the treatment of nutritional anemia due to iron deficiency, whereas the article, because of its vitamin B₁₂ content, was not effective in the treatment of such condition.

DISPOSITION: July 27, 1951. Default decree of condemnation and destruction.

3516. Adulteration of grindelia. U. S. v. 6,666 Pounds * * *. (F. D. C. No. 30944. Sample No. 24012-L.)

LIBEL FILED: May 8, 1951, Southern District of New York.

Alleged Shipment: On or about January 2, 1951, by J. G. Olvey & Associates, from Colusa, Calif.

PRODUCT: 6,666 pounds of *grindelia* in 31 unlabeled bales at New York, N. Y. Examination of 6 samples showed that the article contained 25%, 25%, 50%, 12.5%, 12.5%, and 33.3% of stems over 2 mm. in diameter, respectively, in the 6 samples.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Grindelia," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the official standard since the article contained more than 10 percent of its stems over 2 mm. in diameter, the maximum permitted by the standard.

DISPOSITION: June 21, 1951. The Meer Corp., New York., N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency, so that each bale would show its respective stem content, together with the stem content permitted by the National Formulary.

3517. Adulteration and misbranding of prophylactics. U. S. v. 21 Gross * * * (F. D. C. No. 31419. Sample Nos. 16956–L, 16962–L.)

LIBEL FILED: July 2, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about February 7, April 21, and May 12, 1951, by the Ivers Lee Co., from Newark, N. J.

PRODUCT: 21 gross of *prophylactics* at Los Angeles, Calif. Examination of samples showed that 2.8 percent were defective in that they contained holes.

LABEL, IN PART: "Three Roger (O. K.)."

Nature of Charge: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

3518. Misbranding of Sleepene tablets. U. S. v. 32 Bottles * * * (F. D. C. No. 31213. Sample No. 23532-L.)

LIBEL FILED: June 22, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about February 1, 1951, by the Sleepene Co., Inc., from New York, N. Y.

PRODUCT: 32 125-tablet bottles of Sleepene at Hackensack, N. J.

Label, in Part: "Tablets Sleepene * * * Active Ingredients Aluminum Hydroxide, Acetylsalicylic Acid (Aspirin), Magnesium Trisilicate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Sleepene Helps You Sleep if insomnia is due to simple irritability, nervousness or tension" was false and misleading since the article would not help one sleep.

Disposition: August 14, 1951. Default decree of condemnation and destruction.

3519. Misbranding of Dr. Pierre's Boro-Pheno-Form suppositories. U. S. v. 24 Boxes, etc. (F. D. C. No. 29978. Sample No. 84801-K.)

Libel Filed: November 3, 1950, Southern District of Ohio.

ALLEGED SHIPMENT: On or about September 29, 1950, by the Dr. Pierre Chemical Co., from Chicago, Ill.

Product: 24 boxes, each containing 12 packages, of *Dr. Pierre's Boro-Pheno-Form suppositories* at Dayton, Ohio, together with a number of accompanying leaflets entitled "Feminine Hygiene The Boro-Pheno-Form Way."

Analysis showed that the product contained approximately 14.5 percent boric acid and 3.5 percent quinine sulfate, together with salicylic acid, zinc phenolsulfonate, menthenamine, red cinchona bark, zinc sulfate, cocoa butter, and paraffin.

Label, in Part: (Package) "Dr. Pierre's Boro-Pheno-Form 12 Suppositories."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing on the package label and in the leaflets were false and misleading since the statements represented and suggested that the article was effective for promoting personal cleanliness and feminine hygiene, whereas the article was not effective for such purposes.

DISPOSITION: August 3, 1951. Default decree of destruction.

3520. Misbranding of Buno Medicine. U. S. v. 80 Bottles * * * (F. D. C. No. 31030. Sample No. 2890-L.)

^{*}See also Nos. 3503, 3505, 3508, 3510-3515, 3517.

LIBEL FILED: May 4, 1951, Southern District of West Viriginia.

ALLEGED SHIPMENT: On or about March 27, 1951, by Buno Co., Inc., from Philadelphia, Pa.

PRODUCT: 34 1-pint bottles and 46 8-ounce bottles of Buno Medicine at Charleston, W. Va.

Label, in Part: "Buno Double Strength Medicine Resorcinol Cantharides Lycopodium Alcohol 38%."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "In Treatment of Stubborn or Severe Cases of Dandruff, Alopecia, Psoriasis, Eczema and Various other Skin and Scalp Disorders or Diseases" was false and misleading since the article was not effective in the treatment of such conditions.

DISPOSITION: July 2, 1951. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3501 TO 3520

PRODUCTS

N	J. No.		N. J. No.
Acetyl-amino-benzaldehyde-thio-		Donnatal tablets	3504
semicarbazone tablets	3501	Estrotron	3513
Amphetamine sulfate (powder),		Grindelia	3516
dl	3507	Hemotene tablets	_ 3515
Ascorbic acid tablets	3503	Oil-acid-iodine	. 3506
Belladonna, tincture of	3508	Phenobarbital, elixir of	_ 3503
Benzedrine Sulfate tablets	3504	Pierre's, Dr., Boro-Pheno-Form	1
Boro-Pheno-Form suppositories,		suppositories	_ 3519
Dr. Pierre's	3519	Premestrone (conjugated estro	-
Buno Medicine	3520	gens)	3514
Cogenat tablets (conjugated es-		Prophylactics	3517
trogens)	3511	Rutin and ascorbic acid tablets.	_ 3503
Conjugated estrogens 3510-3512,	3514	Sleepene tablets	3518
Conjugens tablets (conjugated		Stilbestrol tablets	_ 3503
estrogens)	3512	Sulfamerazine tablets	3503
Conjugestoral tablets (conju-	0540	Suppositories, Dr. Pierre's Boro	_
gated estrogens)	3512	Pheno-Form	
Devices 3505,		TB-1. See Acetyl-amino-benzal	
Dexedrine Sulfate tablets	3504	dehyde-thiosemicarbazone tab	
Dextro-amphetamine phosphate		lets.	
tablets and dextro-ampheta-	3503	Tetraethylthiuram disulfide	3502
mine sulfate tablets	5005	Tuinal capsules	
Diphenylhydantoin sodium cap- sules	3509	Veterinary preparation	
	9909	Violetta kits	
Dl-amphetamine sulfate (pow-	2507	Vitamin preparation	
der)	2001	vitamin preparation	. 9019

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N.	J. No.		N. J. No.
Arenol Chemical Corp.: dl-amphetamine sulfate (pow-		Olvey, J. G., & Associates: grindelia	3516
der)	3507	Pacific States Laboratories, Inc.	
Buno Co., Inc.:		TB-1-PSL tablets	
Buno Medicine	3520	Pierre. Dr., Chemical Co.:	. 5501
Corby-Franklin Associates:		Dr. Pierre's Boro-Pheno-Form	,
Conjugestoral tablets (conju-		suppositories	
gated estrogens)	3512	Pitman-Moore Co.:	. 9919
Doctors' Mutual Service Co.:		Estrotron	3513
Premestrone (conjugated es-		Red Star Chemical Co., Inc.:	. 9919
trogens)	3514	tetraethylthiuram disulfide	2500
Electro-Technic Products:		Richlyn Laboratories:	3502
Violetta kits	3505	diphenylhydantoin sodium cap	
Hopkins, M. P.:			
amphetamine sulfate dextroro-		sulesSleepene Co., Inc.:	. 3509
tatory tablets, amphetamine		Sleepene tablets	0510
phosphate dextrorotatory			. 3518
tablets, rutin and ascorbic		Specific Bio-Chemicals:	
acid tablets, ascorbic acid		Premestrone (conjugated estro-	
tablets, sulfamerazine tab-		gens)	. 3514
lets, stilbestrol tablets, and		Standard Drug Co., Inc.:	0=00
elixir of phenobarbital	3503	tincture of belladonna	3508
Hopkins & Hopkins Pharmaceu-		Success Chemical Co., Inc.:	
tical Co.:		Conjugens tablets and Conju	
. amphetamine sulfate dextro-		gestoral tablets (conjugated	
rotatory tablets, ampheta-		estrogens)	. 3512
mine phosphate dextrorota-		U. S. Factors:	0504
tory tablets, rutin and ascor-		TB-1-PSL tablets	3501
bic acid tablets, ascorbic acid		Whitmoyer Laboratories, Inc.:	0=00
tablets, sulfamerazine tab-		oil-acid-iodine	. 3506
lets, stilbestrol tablets, and		Wiles, C. B., and W. P.:	
elixir of phenobarbital	3503	Donnatal tablets, Benzedrine	
Ivers Lee Co.:		Sulfate tablets, Tuinal cap	
prophylactics	3517	sules, and Dexedrine Sulfate	
Midwest Chemical Development		tablets	3504
Corp.:		Wiles Drug Store:	
Hemotene tablets	3515	Donnatal tablets, Benzedrine	
National Drug Co.:		Sulfate tablets, Tuinal cap	
Cogenat tablets (conjugated	0.54.5	sules, and Dexedrine Sulfate	
estrogens)	3511	tablets	_ 3504

•





The Primary Source of Administrative Law

The Federal Register publishes the full text of administrative law as it is created from day to day by Federal executive agencies. This official publication contains proclamations, Executive orders, and regulations of general applicability and legal effect. It is the key to the following subjects and many more in the field of administrative law:

Agriculture
Aliens
Atomic Energy
Aviation
Business Credit
Communications
Customs
Fair Trade Practice
Food and Drugs
Foreign Relations
and Trade
Housing
Labor Relations

Marketing
Military Affairs
Money and Finance
Patents
Public Contracts
Public Lands
Securities
Shipping
Social Security
Taxation
Transportation
Utilities
Veterans' Affairs
Wages and Hours

A SAMPLE COPY AND INFORMATION MAY BE OBTAINED ON REQUEST TO THE FEDERAL REGISTER, NATIONAL ARCHIVES, WASHINGTON 25, D. C.

Order from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

\$1.50 per month

\$15 per year